



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 22, 2022

Desiree Valentin
Regulatory Assurance Specialist
Lonza, LLC
412 Mount Kemble Ave.
Suite 200S
Morristown, NJ 07960

Subject: Label Amendment: Adding Efficacy Claims-SARS-CoV-2,
Marketing claims, additional types of surfaces, Qualified germ claim to
support use of "germs" claim to the master label.
Product Name: Nugen® NR-RTU
EPA Registration Number: 6836-445
Application Date: 09/23/2021
Action Case Number: 00324061

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. 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 the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the

website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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

Sincerely,

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

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

Enclosure: Stamped 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*]

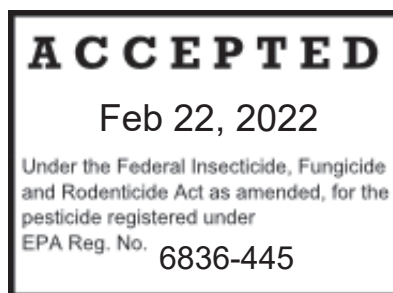
For Home, Commercial, Institutional and Industrial Use
For Food, Dairy, Beverage, Meat, Poultry, Egg and Seafood Processing and Farm Use
For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use
For use in federally inspected meat and poultry plants
An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

Active Ingredients:

Poly(hexamethyleneguanide) hydrochloride0.0534%
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



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

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 Easy [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] chemically balanced 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
- Leaves no harsh chemical residue
- Low odor
- Low streak formula
- Makes [your job] [cleaning] [easier] [easy]
- 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 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 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 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 [disinfects] [sanitizes]^{1, 2}
- Cleans and [disinfects] in one step^{1, 2}
- Convenient 4 minute hospital disinfection¹
- Kills bacteria
- Daily [Surface] [Disinfectant] [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 surfaces 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[s] [baby] [children's] [kids] [and] [pet] toys ¹
- 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 germs ⁷
- Effective against SARS-Related Coronavirus 2 [SARS-CoV-2] [USA-WA1/2020] [in 1 minute] ¹
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 virus, the cause of COVID-19
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2 [virus]
- [Even] Disinfect[s] areas where you prepare and eat food
- [Everyday] worry free [disinfectant] [disinfecting]
- Everyday [surface¹] [disinfectant] [sanitizer] [cleaner]
- Effective in [disinfecting] [sanitizing] [your] [household] [kitchen] [bathroom] [surfaces¹]
- Effectively disinfects 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
- Kills [99.9% of] SARS-CoV-2, 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]
- Hassle-free [disinfection] [sanitization]
- 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]
- 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] 99.9% of foodservice bacteria¹
- [Kills] [Removes] [Destroys] 99.99% of foodservice germs⁷ [Escherichia coli [E. coli], Salmonella enterica [Salmonella], and Listeria monocytogenes [Listeria] ¹
- 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] on hard, non-porous surfaces
- [Kills] [Tested and proven effective against] COVID-19 Virus 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

- Reduce risk of cross contamination between treated surfaces [on hard non-porous surfaces]
- Remove [99.9% of] [bacteria] [from your] [surfaces'] [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 [contact] surface sanitization and no-rinse disinfection¹
- [Multi-functional] antimicrobial for [food contact][kitchen] hard, non-porous surfaces
- [Disinfect] [Sanitize] [baby] [children's] toys¹
- [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] [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] 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] [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] [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 minutes¹
- [Proven to] kill[s] coronavirus⁶
- [Proven to] kill[s] the virus⁶ that causes COVID-19
- [Proven to] wipe out² 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 step]²
- [With proven] antibacterial action
- Wipes out² 99.9% of COVID-19-causing coronavirus^{3,6}
- Wipes out² 99.9% of [the] COVID-19-causing virus^{3,6}
- Worry free [disinfecting]

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 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]
- Multi-purpose¹
- Multi-surface¹
- Specially formulated for use in the [kitchen] [bathroom]

SURFACE SAFETY CLAIMS:

- [Gentle on] [Safe for] hard non-porous surfaces, tough on germs⁷
- Safe to/[Safe for] use on [household surfaces] [such as][insert areas of use][insert types of surfaces]
- [Safe for] use on [high traffic] [high touch][commonly touched] hard, non-porous surfaces
- [Safe for] use [on hard, non-porous surfaces] [in areas] where you prepare [and][or] [eat] food
- 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:

- 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 dyes][,] [No Harsh Fragrances][,][No need to rinse][No rinse]
- No harsh chemical residue
- 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 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 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 RTU**:

Bathrooms
Children's rooms
Dens
Family rooms
Homes [households]
Kitchens
Living room
Dental offices
Hospitals
Medical Offices
Nursing homes
Bars
Breakrooms
Cafeterias
Convenience stores
Dining halls

Food storage areas
Restaurants [Front of House] [Dining & Eating Areas]
Restaurants [back of house] [kitchen]

Airplanes
Airports
Ambulance(s)
Automobiles
Boats
Boxcars
Buses
Campers
Cars
Cruise ships
Delivery trucks
Emergency [Police] [EMS] [Fire] [Rescue] vehicles
Food trucks
Mobile food establishments
Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

Athletic facilities
Banks
Banquet Halls
Barber / Beauty shops
Beverage processing facilities
Business and office buildings
Caterers / Catering facilities
Colleges
Correctional facilities
Dairy processing plants
Day care centers
Delicatessens
Dressing rooms
Exercise facilities
Factories
Fitness centers
Food manufacturing facilities
Food packaging facilities
Food processing facilities
Food service facilities
Grocery
Gyms
Health clubs
Hospitals
Hotels
Institutional facilities
Institutions
Laundry rooms
Locker rooms
Motels
Nurseries
Nursing homes
Playrooms
[Poultry][Meat/Seafood Packing] Facilities
Prisons
Public facilities
Public rest rooms
Salons
Schools
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 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	Kid['s][s] Toys ¹
Appliances	Pacifiers
Bar tops	Pet Bowls
Bathroom fixtures	Pet Toys ¹
Bathtubs [Fiberglass]	Self-service condiment areas
Beverage [machine or dispensers] ³	Self-service service ware areas
Booster seats[Dining] Booths	Showers
Broilers ³	Shopping cart handles
Cabinets	Shopping carts / baskets
Cafeteria trays	Shower [stalls] [walls]
Cages	Sinks [bathroom, kitchen]
Car seat	Slicers
Cash registers	Storage areas
Chairs	Stoves [stovetops] ³
Changing tables	Strollers
Children's Toys ¹	Tables, [picnic tables] [Dining Tables]
Coffee machines	Tanning Beds
Computer keyboards	Telephones
Cooking surfaces ³	Toasters ³
Coolers	Exterior Toilet bowl surfaces
Condiment containers	Toilet seats
Cribs	Touchscreens
Counters [countertops]	Toys ¹
[Bathrooms] [Kitchen] [Restaurant]	Trays [high chair] [hospital]
Cupboards	Tub walls
Desks	Tubs
Diaper changing [tables] [counters]	Tiles, glazed
Diaper pails	Walls
Digital devices	Trashcans
Dining tables	Trays
Dish racks	Food Trays
Doorknobs	Self-service condiment areas
Door handles	Self-service serviceware areas
Drain boards	Host/Hostess Stations
Equipment tables	Laminated Menus
Faucets	Lawn chairs
Faucet Handles	Beverage Dispensers
Floors	
Finished floors	Other hard non-porous surfaces made of:
Food mixers	Acrylic
Garbage cans	Finished woodwork
Glass	Formica®
Griddles ³	Glass
Grills ³	Glazed ceramic
Gym mats	Glazed enameled surfaces
Hampers	Glazed porcelain
Headsets	Metal
Highchairs	Plastic [such as polystyrene or polypropylene]
Ice machines [doors][tracks][ice chutes][ice	Sealed granite

bins][ceiling][wall][ice scoop][ice cube tray]³
 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

Sealed marble
 Sealed quartz
 Sealed stone
 Stainless steel
 Upholstery- vinyl and plastic

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]
Shigella sonnei [ATCC 25931]
Yersinia enterocolitica [ATCC 23715]
Vibrio cholera [ATCC 14035]

[Viruses*:]

*HIV-1 [AIDS Virus] [HTLV-IIIb]
 *Human Norovirus [ATCC VR-782]
 *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 surfaces in 30 60 seconds against:

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

NON-FOOD CONTACT SANITIZATION CLAIMS:

NUGEN® NR RTU is an effective sanitizer for use on non-food contact surfaces in 15 seconds 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.

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 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 RTU [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 ~~60~~ 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.
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.

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

⁶ SARS-CoV-2

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

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



Kids Toys



Kids Toys



Baby Toys



Pet Toys



Playrooms



Playrooms



Playrooms

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

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

{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 harsh [chemical] residue, No worries
 - Rinse free, [for] worry free [disinfecting]
 - Use [in areas] [on hard, non-porous surfaces] where [kids] [children][and] [pets] [play]
 - [Thoughtfully] [Expertly] [formulated] [to] [help protect your] [family] [loved ones], [even] [in homes with children & pets]
 - [Expertly][Thoughtfully] formulated for use in homes [with children and pets]
 - Tough on germs⁷, but gentle on your hard, non-porous surfaces
 - Gentle on hard surfaces [even][including] where [kids] [and] [pets] [play]
 - Gentle on hard surfaces, not on germs⁷
-
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