

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 30, 2017

Jonathan Walsh Regulatory Assurance Specialist Lonza, Inc. 90 Boroline Road Allendale, NJ 07401

Subject: Label Amendment – To update label language

Product Name: NuGenTM 2M Disinfectant Wipes

EPA Registration Number: 6836-372 Application Date: December 29, 2016

Decision Number: 526546

Dear Mr. Walsh:

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 Emilia Oiguenblik by phone

Page 2 of 2 EPA Reg. No. 6836-372 Decision No. 526546

at 703 347 0199, or via email at <u>Oiguenblik.emilia@epa.gov</u> or Eric Miederhoff by phone at 703 347 8028, or via email at <u>Miederhoff.eric@epa.gov</u>.

Sincerely,

Eric Miederhoff

Eric Miederhoff

Product Manager 31

Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Stamped label

Note to Reviewer:

[Language in brackets [AAA] is optional or interchangeable]

{Language in braces {AAA} is for informational purposes and will not appear on the final label}

NUGEN™ 2M Disinfectant Wipes

[One Step Cleaner] / [Disinfectant] / [Deodorizer] / [Virucide*] / [Virucidal*] / [Bactericidal] / [Bactericide] / [Germicidal¹]

Active Ingredients:

Poly(hexamethylenebiguanide) hydrochloride	0.0890%
Octyl decyl dimethyl ammonium chloride	0.1333%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium choride	0.0799%
Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	0.1778%
[Other][Inert] Ingredients:	<u>99.4666%</u>
Total	100.0000%

WARNING [AVISO]

See [left] [side] [right] [back] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-372

EPA Est. No. (as indicated on container)

Net Contents: (insert #) [premoistened] [towelettes] [wipes] [disinfecting] [antibacterial] [cleaning] [wet] [multi-purpose] [touch-

up] [pre-moistened cloths] [sheets]

[Net Contents: [expressed as avoirdupois pounds and ounces]]

[optional: wipe dimensions:] X x X [inches] [in.]

[Net Weight: [expressed as avoirdupois pounds and ounces]]

[DOT Symbols] [Barcode] [QR code]

{Note to Reviewer: for multi-packs}

[2-pack]

[[Bonus] Twin pack]

[3-pack]

Manufactured by: Lonza Inc. 90 Boroline Road Allendale, NJ 07401

ACCEPTED

03/30/2017

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

6836-372

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

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Do not get in eyes. Avoid contact with skin and clothing. Wear protective gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye.

IF ON SKIN: 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.

Call a poison control center or doctor for treatment advice. 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.]

{Note to reviewer: Pages 3-18 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 [Convenient] [Amazing] Package
- New easy to dispense
- New Easy [Start Lid] [Start Package] [Grab Lid]
- New EZ [to start lid] [start package] [Grab Lid]
- New, faster acting [disinfecting] [antimicrobial] [cleaning] [wipes]!
- New larger [bigger]-sized wipe
- New Larger Size
- New [thick] [textured] wipe
- New Top
- New tougher wipe for tougher cleaning
- New tougher wipe for your tough[er] jobs
- New Wipes
- [New] [Now] [less-residue] [low-residue] [low-streak] formula

General Claims

- [2] [Two] minute contact time* [*Excluding [list organisms greater than two minutes]]
- Can help reduce cross-contamination on hard nonporous treated surfaces [in the] [kitchen] [school]
 [classroom] [bathroom] [restroom] [household] [office] [work]
- Daily defense against [germs] [pathogens]
- Designed for healthcare use
- [Designed] [Ideal] for daily [cleaning] [use]
- Disinfects in [just] [two] [2] minutes
- Easy on surfaces
- For use in critical care areas [where control of the hazards of cross contamination between treated surfaces is of prime importance]
- · For daily defense against outbreaks in your hospital
- For healthcare use
- For hospital use
- For long-term care facility use
- Helps prevent cross contamination on treated surfaces
- Hospital [cleaner] disinfectant [cleaner]
- [Kills] [Effective against] [Wipes out] [Eliminates] [organisms listed on table xx] in just [2] [two] minutes {Note to reviewer: "table xx" refers to organisms from the list on page 17 which will be presented in table format on a final printed label}
- Reduces risk of cross contamination on hard non-porous treated surfaces [This product] [product name] is a
 one-step [hospital use] [germicidal] [disinfectant] [cleaner] [and] [deodorant] [odor counteractant] [odor
 neutralizer] designed for general cleaning [and] disinfecting [and] [deodorizing] [of] hard nonporous
 [inanimate] treated surfaces
- [Wipes out] [Kills] [Eliminates] [list organisms] in just [2] [two] minutes

CLEANING CLAIMS:

- [A] Clean you can trust
- [All] [Multi-purpose] kitchen [everyday] [daily] [touch-up] [cleaning]
- Clean more with less
- Clean to a virtually streak-free shine
- Clean with just a wipe or a touch up
- Cleaning
- Cleaning just got a whole lot easier
- Cleans
- Cleans [grease] better than ever
- · Cleans more than ever
- Cleans things you never thought a wipe could
- Cleans to a [Sparkle] [Shine]
- Clean, disinfectant and protect in one step
- Convenience of a wipe [a cloth]
- Convenient
- Cuts through [tough] [dirt] [stains] [grime] [soils] [dried on stains] [dried on soils]
- Cuts Through [Tough] [Messes] [Grease] [Grime]
- [Everyday] [Regular] [Cleaning] Wipes
- [Everyday] [Regular] Cleaning
- [Everyday] [Regular] Wiping
- Extra Power for your tough cleaning jobs
- Extra Power wipe for cleaning extra tough [jobs] [messes]
- Fast drying; leaves no dull or sticky residue
- Faster acting [wipe] formula
- For [light touch ups] [quick clean-ups] [in one easy step]
- For a Powerful Clean
- For everyday messes
- For the quick touch ups, try (Brand)
- For when a regular wipe [just] can't get the job done
- Gets up stuck-on messes [so you don't have to get on hands and knees]
- Grease cleaning power
- Greasy messes
- [Great] [Designed] [Built] [Tough] [Textured Design] for your Toughest Messes
- [Great] [Designed] [Built] for Tough [Messes] [Cleaning]
- [Great] for [Spring] [Home] [Kitchen] [Bathroom] [Dorm] [Office] [Cart] [Car] Cleaning
- [Great] for Cleaning Your [Home] [Kitchen] [Bathroom] [Room] [Dorm] [Office] [Cart] [Car]
- Great for Cleaning [classrooms][and][schools]
- Great for cleaning around the toilet
- Grimy messes
- Handles daily clean-ups with no need for additional sprays, sponges or buckets.
- Heavy [light] duty [jobs]
- Helps you finish [cleaning] fast [quickly]
- Ideal for use as a [daily][spot] cleaning wipe [in hospitals]
- Leaves [no residue]
- Leaves your [house] [bathroom] [kitchen] fresh and clean
- Life doesn't stop for messes, [Wipe] [Clean] it up
- Life is Messy, [Wipe] [Clean] it up
- [Long lasting] [lasts a long time] [goes further] [last longer]
- Low-streak formula is great on [glass] [mirrors] [stainless steel] [stainless]
- Makes [your job] [cleaning] [easier] [easy]
- More scrubbing power
- No [mixing] [spraying] [mess] [and / or fuss] [no muss]

- No more need to get on your hands and knees to [scrub] [or clean] stubborn spots.
- No rinsing required
- No sprays, no sponges, no mess
- Now cleaning is [faster] [easier] than [ever] [before]
- Now cleans better on grease
- One step [clean] [cleaning]
- Picks up more messes than other wipes
- Powerful cleaner for kitchen and bath
- Powers through [tough messes] [the dirt] [the grime]
- Powers through tough messes
- Powers through tough messes all over the house
- Quick easy clean-ups.
- Removes the grime to give you more time [alt: Removes the grime so you have more time]
- [Scrubs] [cleans] better
- Sticky messes
- Streakfree
- The convenient way to keep your home looking "just cleaned"
- The wipe to use when you don't have much time
- Touch Up
- Tough cleaning [made easy] [made easier] [at your fingertips]
- Tough Cleaning at your Fingertips!
- Tough cleaning without the tough cleaning smell
- Tough Enough to Clean a Classroom
- Tough enough to do the bigger cleaning jobs.
- Traps & locks away [dirt] [grease] [messes] [crumbs] [hair] [lint] [dust] [dirty greasy messes]
- Traps and locks grease and grime
- Use [daily] to clean bathroom soils such as soap, soap scum, toothpaste, hair spray, hair gel, cosmetics, shaving cream, hand or body lotion.
- Wipe down your seat. Bring [wet] [wipes] [or] [handi-wipes] to wipe down the [arm rests] [window areas] [seatbelt clasps] [and] [tray table] where you'll be sitting.
- Wipes are good for quick touchups
- Wipes Away [Tough] [Everyday] [Messes] [Grease] [Grime]
- Wipes Out [Tough] [Everyday] [Messes] [Grease] [Grime]
- Wipes Through [Tough] [Everyday] [Messes] [Grease] [Grime]
- Wipes to a [Clean] Shine [Sparkle]
- Wipes Up [Tough] [Everyday] [Messes] [Grease] [Grime]
- Worry free cleaning

FRESHNESS AND ODOR ELIMINATION CLAIMS:

- Deodorizes
- Don't just mask odors [eliminate][neutralize] them
- [Eliminates][Neutralizes] odors [and freshens] on contact
- For a cleaner, fresher [home] [house], great for [all around] the [house] [home] [kitchen] [bath]
- For a long lasting scent experience
- Fresh, clean scent
- Leaves a [light] [clean] [fresh] scent
- Leaves a clean, fresh scent
- Light, clean scent
- Long lasting scent
- Powers through odor
- Tough on odor
- Wipes out odors

Scent Names

[Note to reviewer: each block below also represents a graphic depicting the corresponding scent with the			
exception of citrus, apple, and berries, which will be submitted to the Agency for review.}			
• [with] [a] [scent name] [scent] [fragrance]	• [Fresh] [Crushed] Citrus	Clean and Fresh	
• [scent names]	 Fresh Linen 	Oakwood	
Wintergreen	 Evergreen 	Pine	
Herbal	Green Tea	• Lilac	

Ocean Tide

Lemon Lime

Sunfresh

Island Escape

CLEANING AND ODOR ELIMINATION CLAIMS:

A fresh take on tough cleaning

[Piercing] Lemon

Lemon Verbena

- An effective way to clean and deodorize against odor-causing bacteria.
- Eliminate dirt and [neutralize] odor

[Fabulous] Lavender

- Freshens [as you clean]
- [Helps][Kill][s][Eliminate][s] odor-causing bacteria
- Kills odor causing bacteria
- Power[s] through [tough] [messes] [dirt] [and grease] and [help[s]] [eliminate[s]][neutralize[s]] odors

ANTIMICROBIAL CLAIMS:

- 3 [steps] in 1- wipes, scrubs and disinfects [so you finish faster]
- All around the house [disinfecting] [cleaning formula]
- Antibacterial
- Antibacterial Formula
- [Antimicrobial] [antibacterial] [disinfecting]
- Bacteria that grows in the shower/bathroom
- Broad spectrum [hospital] cleaner disinfectant
- Clean and [Disinfect] from Classroom to Playground Equipment
- [Clean and] [disinfect] in just [2] [two] minutes
- [Clean and] [disinfect] [commonly touched] [household] surfaces in [just] minutes[!]
- Cleans and [disinfects] [without scratching] [surfaces]
- Cleans [and] [disinfects] [deodorizes] in one [easy] step [on hard non-porous surfaces]
- Cleans up stubborn messes while it [disinfects]
- Cuts [tough] grease, kills bacteria
- Daily [Surface] [Disinfector] [Cleaner]
- [Designed] [Built] for [disinfecting] and [cleaning] [wiping] everyday messes
- [Designed] [Built] for Everyday [Disinfecting] [Cleaning] [Wiping] [Messes]
- [Disinfect] [airplane][airliner] [tray[s]] [tray table[s]]
- [Disinfect] any room in the house
- [Disinfect] [baby][children's] toys
- [Disinfect] [bathroom][kitchen] [sink[s]] [faucet[s]] [toilet[s]] [flush handle][seat] [light switch] [door][handle][knob]
- [Disinfect] [camping][hiking][boating] equipment
- [Disinfect] [cell][mobile][phones]
- Disinfect [commonly touched] [household] surfaces
- [Disinfect] [computers[s]][keyboards] [touchpads] [mouse]
- [Disinfect] [daycare][childcare] [facilities]
- [Disinfect] [desk tops] [work tables] [work areas] [school desks] [shared equipment]
- [Disinfect] [hotel][motel][public][shared] [TV][television[s]] [remote control[s]][remote[s]]
 [telephone[s]][phone[s]] [computer[s]][keyboard[s]] [fax machine[s]]

- [Disinfect] [shopping][grocery] cart[s] [handle[s]]
- [Disinfect] [Surfaces] [Your House] [Your Kitchen] [Your Bathroom] [Daily] [Everyday]
- [Disinfect] 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] 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] the hard, non-porous surfaces of [sports][sporting][gym][athletic][workout] [equipment][machines]
- [Disinfect] the hard, non-porous surfaces of [wrestling][gymnastic][gym][athletic][yoga][tumbling]
 [mats][pads]
- [Disinfect] the [interior][exterior] of [common] [household][kitchen] appliances
- [Disinfect] [waiting rooms] [public areas]
- [Disinfect] [your][common] [household] [surfaces][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] [Your Desk] [Your Office] [Your Room] [Daily] [Everyday]
- [Disinfecting] Formula
- [Disinfecting] Wipes
- [Disinfects] [as it cleans] [and scrubs in one easy step] [without [a] [the] [that] disinfectant smell]
- [Disinfects] while cleaning [up] stubborn messes
- [Easy] way to [clean and] disinfect [in one step]
- Effective against bacteria
- Effective against [Staph] Staphylococcus aureus Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]] [Staphylococcus aureus Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]] [Staphylococcus aureus Methicillin-Resistant [MRSA]][Staphylococcus aureus Multi-Drug Resistant [resistant to tetracycline [Tc], penicillin [Pc], erythromycin [Em] and Clindamycin][Staphylococcus aureus Vancomycin Intermediate Resistant [VISA]] [Staphylococcus aureus Vancomycin Resistant [VRSA]] [Klebsiella] [ESBL Klebsiella pneumoniae] [Klebsiella pneumoniae NDM-1 Positive] [Campylobacter] [Campylobacter jejuni]
- Effective in disinfecting [your][household][kitchen][bathroom][surfaces]
- Effective one-step disinfectant cleaner for use in [hospitals][ambulatory care centers][long-term care facilities][and other healthcare settings]
- Effective in the presence of 5% serum contamination
- Effectively [disinfects] common household surfaces
- Eliminate bacteria in [just] 2 minutes[!]
- Eliminates [Pseudomonas] [Pseudomonas aeruginosa] [MRSA] [CA-MRSA] [E.coli] [Campylobacter jejuni] [VRE] [Salmonella enterica] [Salmonella] [Salmonella enterica serovar Typhi] in [just] 2 minutes[!]
- Everyday [Surface] [Disinfectant] [Cleaner]
- [Finally] a wipe that cleans and [disinfects]
- Great for Everyday [Disinfecting] [Cleaning] [Wiping] [Messes]
- Hospital Disinfectant
- Kills bacteria
- Kills Germs² [Bacteria] [Viruses] [Bacteria and Viruses]
- Kills [Staph] [Staphylococcus aureus Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]] [Staphylococcus aureus Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]][Staphylococcus aureus Methicillin-Resistant [MRSA]][Staphylococcus aureus Multi-Drug Resistant [resistant to tetracycline [Tc], penicillin [Pc], erythromycin [Em] and Clindamycin][Staphylococcus aureus Vancomycin Intermediate Resistant [VISA]] [Staphylococcus aureus Vancomycin Resistant [VRSA]] [Klebsiella] [ESBL Klebsiella pneumoniae] [Klebsiella pneumoniae NDM-1 Positive] [Campylobacter] [Campylobacter jejuni]

- Kills bacteria [while it cleans]
- Kills Cold & Flu Virus
- Kills common household bacteria
- Kills common [household] [kitchen][bathroom] bacteria
- [Kills] [Eliminates] [Destroys] germs² [in] [just] [2 minutes]
- [Kills] [Eliminates] [Removes] [Destroys] (Insert pathogen or pathogens other than avian Influenza A from lists on pages 16-17) [on [pre-cleaned] environmental surfaces]
- [Kills] [Eliminates] [Removes] [Destroys] bacteria
- [Kills] [Eliminates] [Removes] [Destroys] bacteria, leaves [leaving] surfaces [clean and] disinfected
- [Kills] [Eliminates] [Removes] [Destroys] Avian Influenza A H3N2 [and] H5N1 on pre-cleaned environmental surfaces
- [Kills] [Fights] Germs² [Influenza Type A/Brazil, the Flu Virus] [Bacteria] [Bacteria and Viruses] [Viruses]
- [Kills] [Fights] Wipe Out [Germs²] [Influenza Type A, the Flu Virus] [Bacteria] [Viruses]
- Kills germs²
- Kills Salmonella, [Salmonella enterica], [Staphylococcus aureus Methicillin-Resistant [MRSA]] & Flu Virus!
- Kills the Flu Virus* On Hard Nonporous Treated Surfaces
- Kills [Wipes Out] {Listeria] [Listeria monocytogenes] [MRSA] [Methicillin-Resistant Staphylococcus Aureus]
- Leaves surfaces clean and disinfected
- Reduce risk of cross contamination on hard non-porous treated surfaces
- Remove [Bacteria] [Germs²] [from Your] [Surfaces] [Home] [Kitchen] [Bathroom] [Office]
- The convenient way to [disinfect] your household surfaces
- The smart [way to] clean [and disinfect]
- The wipe that [disinfects] while it cleans [up [stubborn] [stuck-on] messes]
- Two in one action [cleans and [disinfects] in one easy step]
- Use to [pre-clean][critical][semi-critical] medical devices prior to [sterilization][high-level disinfection]
- Wipe Away [Germs²] [Influenza Type A, the Flu Virus] [Bacteria] [Viruses*]
- Wipe out germs² [in just minutes]
- Wipe Up [Germs²] [Influenza Type A, the Flu Virus] [Bacteria] [Viruses*]
- [With proven] Antibacterial Action
- Worry free [disinfecting] [cleaning]

H1N1 CLAIMS:

- Kills Pandemic 2009 H1N1 Influenza A virus
- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu)
- Respiratory illnesses attributable to Pandemic 2009 H1N1are caused by Influenza A virus. This
 product [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be
 effective against (Influenza A virus tested and listed on the label) and is expected to inactivate all
 Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus.
- This product has demonstrated effectiveness against (*Influenza A virus tested and listed on the label*) and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- [Effective against][Kills][Disinfects] the H1N1 strain of Influenza A on hard, nonporous surfaces[!]
- [EFFECTIVE AGAINST] [KILLS] [THE] [H1N1] FLU VIRUS
- Influenza Type A [virus] [H1N1]
- [Kills] [Eliminates] [Destroys] [the] H1N1 [Influenza] virus on hard non-porous surfaces

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

USAGE CLAIMS:

- For Homes, Institutional and Industrial Use
- For household surfaces [all around the house] indoor and outdoor
- For use [at home], [away from home], [in public places] [on the go]
- Multi-purpose
- Multi-surface
- [Send] [Bring] [Wipes] to School
- Specially formulated for use in the [kitchen] [bathroom]

VALUE CLAIMS:

- [2] [Two] [1] [One] For You [1] [One] For School
- [2] [Two] Free Cloths
- [Assorted] [Mixed] [Special] [Variety] [Multiple] [Multi] [Bundle] [Pack]
- Back to School [Variety] [Special] [Bundle] [Pack]
- Bonus Size
- Convenient [size]
- Get it done with one
- Large Size, Small Size, Bonus Pack
- · More cleaning in one wipe
- More cleaning power per wipe
- One wipe goes a long way
- One wipe will get it done
- [Special] School [Variety] [Bundle] [Pack]
- Spring Cleaning [Special] [Value] [Bonus] Pack]
- Travel [Size] [pack]
- Value Size
- Variety Pack
- XX% More [Free] Wipes, Bonus Size, [Bonus] [Free] [27-ct] [35-ct] [XX-ct] Wipes, XX for the Price of

SURFACE SAFETY CLAIMS:

- Non-abrasive
- Non-scratch[ing]
- Not recommended for use on computer or television monitor screens.
- These [wipes] [towelettes] [cloths] will not harm [most] surfaces.
- Will not scratch

SUBSTRATE CLAIMS:

- 2 sided wipe
- 2 Sides
- [Cloth-like texture] [Textured] for scrubbing power
- Cloth-like [textured] [strong]
- Cloths [Wipes] quickly remove dirt, spots and smudges
- Dual [action] [purpose] [scrubs] wipes]
- For [Grime] [Tough Messes] [Grease]
- Improved scrubbing texture
- [Our] toughest wipe ever
- Premoistened
- [Premoistened] [wet] disinfecting [textured] [antibacterial] [wipes] [towelettes] [cloths]
- [Quilted Texture] [Textured] to [Scrub] [Power] [Fight] Through Tough Messes
- [Special] [Unique] Texture for Tough Messes
- [Strong] [Thick] wipe
- Strong wipe for Heavy Duty cleaning

SUBSTRATE CLAIMS: (cont.)

- Strong wipe for tougher [jobs] [messes]
- [Substrate] [Wipe] [Towelette] [Cloth] composed of 100% [x%] recycled materials
- [Substrate] [Wipe] [Towelette] [Cloth] composed of 100% [x%] renewable materials
- [Substrate] [Wipe] [Towelette] [Cloth] [material] derived 100% from [wood pulp] [cotton] [cellulose] [recycled cellulose]
- [Textured cloth] gets up stubborn stuck on messes
- Textured [cloths] [towelettes] clean floors faster [and easier]
- Textured [Wipe] [cloth] [towelette] [for tough jobs] [for tough cleaning]
- Textured for better [cleaning] [scrubbing] power
- Textured to Pick Up Particles
- The wipe that is [strong] [durable] [thick] [heavy] enough to scrub [and] [clean]
- Thick [wipe], cloth-like texture
- Thicker, cloth-like feel for tough messes
- Tough like a towel
- Tough [Textured] Wipes
- [Tough] [Thick] wipe[s] for tough [cleaning] [messes]
- Tough wipe for tough cleaning [jobs]
- [Unique] [Special] [Thick] [Quilted] Texture for Tough [Messes] [Cleaning]
- Wipe fabric made from 100% renewable resources
- With extra cleaning power [wipes] [sheets] [cloths]
- With [extra] scrubbing power

PACKAGING CLAIMS:

- Better [package] [dispensing]
- Breakthrough package
- [Convenient] [Hassle-free] [One-hand] dispensing
- Converted with 100% [x%] wind energy
- Dispenses better
- Dispenses Like A Tissue [Tough Like A Cloth [Towel]]
- Dispenses like a tissue, cleans like a cloth
- Easier dispensing
- Easy [dispensing] [Lid]
- Easy dispense [lid] [package]
- Easy dispensing [and] [tough texture] [for the ultimate wipes experience]
- [Easv] [EZ] start
- Easy to [open] [thread] [access lid] [dispense]
- Easy to use
- [Eco-shape Canister]
- Energy Efficient Canister
- Fewer rips, bunches, and snags
- [Just like a tissue box] [Tissue box dispensing]
- Just [pull] [pop] wipe and toss.
- [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]]
- No [more] [pinched fingers] [rips] [tears]
- One at a time [dispensing, like a tissue box]
- One wipe at a time dispensing
- Only use approved refill packs.
- Package breakthrough
- Package is 100% recyclable
- Package contains xx% recycled materials

- Package contains xx% post consumer waste
- Packaged with 100% [x%] wind energy
- Packaging contains XX% [post-consumer waste] [recycled materials]
- Pop up
- Pop and go
- Pop and Clean
- Portable
- Produced with Wind Energy
- Recyclable packaging
- Refill [size] [pack] [Refill for (Brand) container] [tub]
- [Regular] [and] [Everyday] Wipe Pack
- Specially designed package that easily dispenses one at a time
- The product was manufactured with 100% Wind Energy
- [This product was] [Produced] [Manufactured] with [100%] [x%] wind energy

FLOOR MOP CLAIMS:

Fits [insert name of mop]

- Fits (Brand) Tools.
- Fits (Brand)
- Fits (Brand) Mop-Head
- Fits (Brand) Mop Heads
- For Mopping

OTHER CLAIMS:

- [After use], just toss wipe away [in trash][in garbage].
- Ammonia Free [formula]
- Bleach Free [formula]
- Call (Insert phone number)
- Cleaning Advice? Visit (website)
- Comments?
- Contains No Phosphate
- Do not use as a diaper wipe or for personal cleansing.
- 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 scent
- Phosphate free
- Quality Guaranteed
- Questions?
- Ready to Use [Disinfectant][Cleaner]
- Save time with [this product or product name][!]
- Saves steps
- Saves Time
- This product contains no [phosphates or] phosphorous [compounds].

NUGEN 2M Disinfectant Wipes:

- are designed for your toughest tasks.
- [are a heavy duty disinfectant cleaner that] cleans, disinfects and deodorizes in one labor saving step.
- deliver non-acid disinfectant and cleaning performance
- deodorizes by killing microorganisms [bacteria] that cause offensive odors.
- [help] take the hassle out of dispensing disinfecting wipes. .
- help you accomplish things you never thought a wipe could do
- [improves labor results by] controls [controlling] malodors.
- is a complete, chemically balanced disinfectant
- is a [one-step] [hospital] disinfectant cleaner that is effective against a broad spectrum of bacteria when used as directed.
- is a proven "one-step" disinfectant cleaner [wipe] [which is effective in the presence of [5% serum contamination][organic soil]]
- is formulated for use in daily maintenance programs with a balance of detergents, biocides and malodor counteractants that deliver effective cleaning, disinfecting and malodor control.
- [Kills] [eliminates] [kitchen] [bathroom] [household] bacteria.
- [Kills] [eliminates] common household bacteria.
- Kills [eliminates] bacteria
- One step cleaning [and][disinfecting][deodorizing]
- One step disinfectant cleaner
- Starts killing [bacteria] on contact
- will disinfect, clean and deodorize surfaces in rest rooms and toilet areas, sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- will not leave grit or soap scum.
- [wipes] [cloths] [sheets] help you to accomplish things you never thought a wipe could do

Cross-contamination is of major [housekeeping] concern. **NUGEN 2M Disinfectant Wipes** have been formulated to aid in the reduction of cross-contamination in the home, schools, institutions and industry.

Use NUGEN 2M Disinfectant Wipes

- as a disinfectant on hard, nonporous treated surfaces.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and exterior toilet bowl surfaces.
- in federally inspected Meat & Poultry Plants as a disinfectant on all surfaces in inedible product processing areas, non-processing areas and / or exterior areas..
- in kitchens, bathrooms and other household areas.
- to clean and disinfect finished floors, sinks and tubs.
- 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. Rinse all equipment that comes in contact with skin before reuse with warm water, and allow to air dry.
- to clean and disinfect hard non-porous surfaces of gym equipment, exercise machines, wrestling mats and gymnastic equipment.
- (Product name) [is][are] recommended for use in [See List of Use and Surface Sites]

- [Removes][and][or][cleans][insert from list below];
 - [Automotive] Grease
 - Blood
 - Body Oils
 - Coffee
 - Crayon and Pencil [Marks]
 - Dirt
 - Dried on blood
 - Fecal Matter
 - Food [or Greasy][or Oily] Spills
 - Food [Residue][Soils]
 - Splatters and Messes
 - Fruit
 - Grime
 - Mud
 - Other common soils
 - Other organic matter
 - Soap
 - Sticky Food Messes [or Spills]
 - Tough Soils
 - Urine

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

[AREAS OF USE:]

Use NUGEN 2M Disinfectant Wipes in:

Bathrooms
Children's room
Homes [households]

Kitchens Living room

Ambulatory Care Centers Ambulatory Surgical Centers Anesthesia Rooms [Areas]

CAT Lab

Central Service Areas

Central Supply Rooms [Areas]

Critical Care Units Dental offices

Dialysis Clinics [Facilities]

Doctor's Offices Donation Centers

Drawers

Examination Rooms or Areas Emergency Rooms [ER] Eye Surgical Centers

Home Health Care [Settings]

Hospices Hospital Beds Hospitals ICU Areas Isolation Areas Laboratories

Long Term Care Facilities

[Medical] Clinics Medical Offices Nursing homes Nurse's Stations Operating Rooms Opthalmic Offices Orthopedics

Out-Patient [Surgical Centers][Clinics][Facilities]

Patient Rooms [Areas]
Psychiatric Facilities
Public [Care] Areas
Radiology [X-Ray] Rooms

Recovery Rooms Rehabilitation Centers Respiratory Centers

Respiratory Therapy Rooms [Areas]

Surgical Centers Waiting Rooms [Areas]

Day care centers

Nurseries

Bars Cafeterias

Commercial Kitchens Convenience stores Food processing plants Food storage areas Institutional kitchens

Restaurants

USDA inspected food processing facilities

Athletic facilities Barber shops

Business and office buildings

Colleges

Correctional facilities Dressing rooms Exercise facilities

Factories

Family Rooms [Dens]

Health clubs

Food Service Establishments

Hotels

Institutional facilities

Institutions
Laundry rooms
Locker rooms

Lodging Establishments Manufacturing Facilities

Motels
Office Building
Pet Shops
Pharmacies
Physician's Offices

Playrooms Prisons Public facilities

Public facilities
Public rest rooms
Reception

Recreational Facilities

Restrooms Retail Businesses

Salons Schools

Shower and bath areas

Sick rooms Universities Veterinary Clinics

Camp grounds

Playground equipment

NUGEN™ 2M Disinfectant Wipes EPA Reg. No. 6836-372 EPA Submission 2017-02-27 [AREAS OF USE:] (cont.)

Airplanes Mobile homes

[Emergency Medical] Transport VehiclesShipsAirportsTaxisAmbulancesTrailersBoatsTrains

Cruise Ships Transportation terminals

Buses Campers Cars

Emergency [Police] [EMS] [Fire] [Rescue] vehicles

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

[TYPES OF SURFACES:]

Use NUGEN 2M Disinfectant Wipes on washable hard, nonporous surfaces of:

Air Vent Exteriors Hard Nonporous Hospital [Medical] Surfaces

Appliances Headboards
Autoclaves Highchairs

Bathroom fixtures [Doorknobs]High Touch SurfacesBathtubs [Fiberglass]Instrument StandsBedpansIV Stands [Poles]

[Bedside] CommodesLab benchesBedside TablesLinoleumCabinet[s] [Handles]Light switchesCagesLaminate flooring

Car seat Non-Wooden Outdoor [patio] furniture except cushion

Carts [Medication Carts] and wood frames\
Chairs Nurse Call [Button][Devices]

Charging Stations

Nuise Call [Button][D

Over-bed Tables

Closet Handles Paddles
Computer keyboards Patient Monitoring Equipment

Computer Peripherals Patient Support and Delivery Equipment Computer Tables Phlebotomy Trays

Computer Tables Phlebotomy Tra
Cords Phone Cradle

Counters [countertops] Physical Therapy Equipment Surfaces

Cupboards Pipe Exteriors
Desks Refrigerators - exteriors

Diagnostic Equipment Refrigerated storage and display equipment

Diaper changing [tables][counters]

Diaper pails

Docking Stations

Scales

Sealed floors

Showers

Doorknobs Shopping cart handles Equipment Surfaces Shower [Fixtures] Equipment tables Shower stalls

Faucets Sinks [bathroom, kitchen]

Faucet Handles Storage areas
Floors Stoves [stovetops]

Finished floors Tables, [picnic tables] [Examination Tables]

Footboards Tanning Beds

Garbage cans Toilet [Seats][Handles][Fixtures]

Glass Toys³Rinse toys with clean, potable water after disinfecting.

NUGEN™ 2M Disinfectant Wipes

EPA Reg. No. 6836-372 EPA Submission 2017-02-27

Page 15 of 26

[TYPES OF SURFACES:] (cont.)

Telephones PVC Tubing
Exterior Toilet bowl surfaces Remote Controls
Side Rails Rescue tools

Side Rails Rescue tools
Slit Lamps Resuscitators

Spine Backboards [Medical] [Hospital] Scales

StoolsStandsStretchersStretchersSupport BarsStethoscopesTubsWalkersTiles, glazedWheel chairs

Walls [In Patient Rooms] Ultra-sound transducers and equipment

Wash Basins

Other hard nonporous surfaces made of:

Non-critical medical device surfaces: Acrylic

Beds [Medical] [Hospital] Finished woodwork

Bed frames Formica®
Bed rails Glass

Crutches Glazed ceramic

Defibrillators Glazed enameled surfaces

Gurneys Glazed porcelain

Mobile Workstations Metal

Mouse pads Plastic [such as polystyrene or polypropylene]

Nonporous Mattresses

Non-critical [hospital] [medical] equipment surfaces

[Medical] Examining tables

[Medical] [Hospital] Lamps

Plastic Mattress Covers

Sealed granite
Sealed marble
Sealed quartz
Sealed stone
Stainless steel

Power Cords Upholstery- vinyl and plastic

Formica[®] is a registered trademark of the Formica Corporation

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

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

NUGEN 2M Disinfectant Wipes are a one-step [Hospital] disinfectant and are Bactericidal according to the current AOAC Towelette Method modified in the presence of 5% organic serum against:

NUGEN 2M Disinfectant Wipes [are effective against] [Kills] [Eliminates] [Removes] [Destroys]:

[Bacteria:]

Pseudomonas aeruginosa [Pseudomonas] Salmonella enterica [Salmonella] Staphylococcus aureus [Staph]

Acinetobacter baumannii

Acinetobacter baumannii, Multi-Drug Resistant [MDR]

Burkholderia cepacia

Campylobacter jejuni [Campylobacter]

Enterobacter aerogenes

Enterococcus faecalis [Enterococcus]

Enterococcus faecalis – Vancomycin Resistant [VRE]

Escherichia coli [E. coli]

Escherichia coli - NDM-1 Positive

Escherichia coli 0157:H7 [E. coli 0157:H7]

ESBL Escherichia coli – [Extended spectrum beta-lactamase producing E. coli]

ESBL Klebsiella pneumoniae

Klebsiella pneumoniae [Klebsiella]

Klebsiella pneumoniae - NDM-1 Positive

Listeria monocytogenes

Proteus vulgaris

Salmonella enterica serovar Typhi [Salmonella]

Serratia marcescens [Serratia]

Shigella dysenteriae [Shigella]

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]

Staphylococcus aureus - Methicillin-Resistant [MRSA]

Staphylococcus aureus - Multi-Drug Resistant [resistant to tetracycline [Tc], penicillin [Pc], erythromycin [Em] and Clindamycin

Staphylococcus aureus - Vancomycin Intermediate Resistant - [VISA]

Staphylococcus aureus - Vancomycin Resistant - [VRSA]

Streptococcus pneumoniae – Penicillin Resistant

Streptococcus pyogenes [a cause of scarlet fever]

Vibrio cholerae

[Viruses:]

- *Hepatitis B Virus [HBV]
- *Hepatitis C Virus [HCV]
- *Herpes Simplex Virus Type 1
- *Herpes Simplex Virus Type 2
- *HIV-1 [AIDS Virus]
- *Human Coronavirus
- *Human Influenza A Virus (H7N9)
- *Influenza A Virus / Hong Kong (H3N2)
- *Respiratory Syncytial Virus [RSV]
- *Rotavirus
- *SARS Associated Coronavirus [SARS] [cause of Severe Acute Respiratory Syndrome]

[Animal Viruses:]

Avian Influenza Virus (H3N2)

Avian Influenza Virus (H5N1)

[Fungi:]

Candida albicans

{For canister}

To Open Package:

Remove cover. Pull up [towelette] [wipe] [cloth] corner from center of roll. Thread through hole in the cover. Replace cover. Open center cap on cover to remove wipe. When not in use [When not using], close center cap [securely] to prevent moisture loss.

or {For carton or tub}

To Open Package: Open cover and slowly peel back label on pouch. Remove [Pull out] [wipe] [towelette] [cloth] as needed. To retain moisture, reseal [pouch] [bag] by firmly pressing seal back on the [pouch] [bag] and close [carton or tub] cover.

or

To Open Package: [Remove package seal[s]] [Remove safety seal[s]] [Flip] Open lid. To remove first wipe [sheet] [wet cloth] cloth] pull up on wipe and remove wipe through [dispensing] opening [wavy dispensing opening] [orifice]. [The next wipe will pop up automatically]. [Always] close [snap] lid securely between uses [to retain moisture].

Of

To Open Package: [Remove package seal[s]] [Remove safety seal[s]]. Open [Flip open lid [package]. To start [remove] [first] wipe [sheet] [wet cloth] take the edge of wipe from large opening to the small dispensing opening and pull up. [The next wipe [sheet] [wet cloth] [cloth] will pop up automatically.] [Always] close [snap] lid securely between uses [to retain moisture].

or

To Open Package: Open Lid. To start wipes, pull up on wipe and move wipe into the small dispensing opening [orifice] [aperture] [hole] [wave] and [pull sheet up to remove wipe] remove wipe. [The next wipe [sheet] [wet cloth] will pop up automatically]. [Always] close [snap] lid securely between uses [to retain moisture].

or

To Open Package: Flip open[up] the lid[cover][top][cap][dispensing lid]. Thread the wipe [first wipe][cloth][first cloth][sheet] through the dispensing lid and pull up to remove wipe from package. The next wipe [sheet][cloth] pops up automatically. Close lid securely between uses to retain moisture[prevent moisture loss].

Of

To Open Package: Press the three [3] ridges with your thumb and push up on the cap[top][lid] to open[lid]. To remove wipe [sheet] [wet cloth] [cloth] [towelette] pull up on wipe and remove wipe through [dispensing] opening [wavy dispensing opening] [orifice]. [The next wipe will pop up automatically].

or

To Open Package: Press the three [3] ridges with your thumb and push up on the cap[top][lid] to open[lid]. Thread the wipe [sheet] [wet cloth] [cloth] [towelette] through the dispensing lid and pull up to remove wipe from package. The next wipe will pop[pull] up automatically. [Always] Close [snap] lid securely between uses [to retain moisture].

Of

To Open Package: Press the three [3] ridges with your thumb and push up on the lid to open. Thread the wipe through the dispensing lid and pull up to remove wipe from package. The next wipe will pop up automatically. Close lid securely between uses to retain moisture.

or

To Open Package: Push the area marked ["Press"] ["Push"] ["Press Here"] ["Push Here"] with your thumb and push up on the lid to open. Thread the wipe through the dispensing lid and pull up to remove wipe from package. The next wipe will pop up automatically. Close lid securely between uses to retain moisture.

or

To Open Package: Open dispenser and top of bag. Pull out the first wipe approximately 6 to 8 inches from the center of the roll. Place the entire bag inside of dispenser. Thread the wipe through the opening on the dispenser lid. Close the lid to retain moisture.

or {For refill, pouch or bag}

To Open Package:

[Slowly] peel back the label [open seal]. Remove [Pull out] [wipe] [towelette] [cloth] as needed. To retain moisture, reseal [pouch] [bag] by firmly pressing seal back on the [pouch] [bag]

or {For the Travel Pack size}

To Open Package: Slowly peel back label. [Pull out] [Remove] [wipes] [towelettes] [cloths] as needed. Reseal label to retain moisture.

or **To Open Package:** Open ziplock [Tear edge of pack]. [Pull out] [Remove] [wipes] [towelettes] [cloths] as needed. Reseal ziplock to retain moisture.

or {For the single cloth or sample pack}

To Open Package: Tear [pouch] open [at top edge of pouch] [at tear notch] [along dotted line] [where indicated] [edge of pack]. [Pull out] [Remove] [Wipe] [Towelette] [Cloth].

{For product supplied in a single use pouch with a folded towellete, include the following:} Unfold [Wipe] [Towelette] [Cloth]

DIRECTIONS FOR USE:

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

Do not use as a diaper wipe or for personal cleansing. This is not a baby wipe!

Do not flush [in toilet.]

For plastic and painted surfaces, spot test on an inconspicuous area before use.

[This product or product name] will not harm most surfaces: including acrylic, sealed fiberglass and vinyl.

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

TO CLEAN AND DEODORIZE:

Wipe surface with [wipe] [towelette] [cloth] [sheet]. Let air dry. Discard used [wipe] [towelette] [cloth] [sheet] in trash.

TO CLEAN AND DISINFECT [DISINFECTION / VIRUCIDAL* DIRECTIONS]:

Wipe [hard, nonporous] surface with [wipe] [towelette] [cloth] [sheet] until surface is visibly wet. [Use enough wipes to thoroughly wet surfaces.] [Use [enough] [extra] wipes to keep surfaces [visibly] wet for 2 minutes.] [Keep surfaces [visibly] wet for 2 minutes.] [Wipe surface and let it remain [visible] wet for 2 minutes.] Allow surface to remain wet for 2 minutes.

{Note to reviewer: if using claims for Serratia marcescens, the following sentence will be required:} [For Serratia marcescens, treated surfaces must remain wet for 5 minutes.]

If surfaces are extremely dirty, clean first with another [wipe] [towelette] [cloth] [sheet] before disinfecting. Discard used [wipe] [towelette] [cloth] [sheet] in trash. Do not flush [in toilet].

Rinse food contact surfaces with clean, potable water after disinfecting. Do not use to disinfect dishes, glassware or utensils.

Fungi: For Candida ablicans control, follow disinfection directions.

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

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that [1] is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or [2] contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. [This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.] {or}

This product is not for use on medical device surfaces.

*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 2M Disinfectant Wipes. NUGEN 2M Disinfectant Wipes [this product] [wipe] [towellete] [cloth] [sheet] can be used for this purpose.

Contact time: Leave surface wet for 2 minutes.

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

To Clean and Disinfect in a Veterinary Application:

Use to clean and disinfect hard, nonporous surfaces such as feeding and watering equipment, cages, utensils, instruments, kennels, stables, catteries, etc. Remove all animals and feed from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings, and manure from walls, floors, and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Pre-clean all surfaces with soap or detergent and rinse with water. Saturate surfaces by wiping with this product and let stand for required contact times. Do not house animals or employ equipment until treated surfaces have been thoroughly rinsed with water and allowed to dry. Thoroughly scrub all treating, feeding, and watering appliances with soap or detergent, and rinse with potable water before re-use.

DIRECTIONS FOR FLOOR WIPE USE:

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

TO CLEAN AND DEODORIZE: Wipe surface with wipe. Let air dry. Discard used wipe in trash.

TO CLEAN AND DISINFECT: Pre-clean floor in normal manner. [Attach a premoistened wipe to the mop head using the [velcro] [fasteners] provided.] Thoroughly wet floor with wipes. [Change wipe when soiled.] or [Replace with a fresh wipe once visibly soiled or no longer thoroughly wetting the surface.] Allow surface to remain visibly wet for 2 minutes. Let air dry. On average, one wipe will clean [x] square feet of floor. For a larger area you may need to use more than one wipe. Discard used wipe in trash. Contact manufacturer of wood floors prior to use.

Do not flush [in toilet.]

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

Do not use on unfinished, oiled or waxed wood, unsealed tiles or carpet.

Keep container flat and lid securely closed to keep cloths moist.

[Optional representative graphic]









TO OPEN:

- 1. Cut off top of pouch with scissors.
- 2. Remove wipes from pouch.
- 3. Place wipes in plastic tub.
- 4. Discard empty pouch into trash.

TO USE WITH MOP:

- 1. Unfold top wipe in tub by pulling sides of the cloth over edges of tub.
- 2. Place sweeper on head
- 3. Wrap wipe around head of sweeper.

- 4. Push edges of wipe into on top of sweeper head.
- 5. Begin wiping. No rinsing required.
- 6. After use, remove soiled wipe and discard in trash. Do not flush.

{Note to reviewer: Nonrefillable container}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Keep securely closed. Nonrefillable container. Do not reuse or refill this container. Discard empty container in trash or recycle [if available].

{Note to reviewer: Refillable container} STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Keep securely closed. Refillable container. [Reuse] [Refill] empty container only with **NUGEN 2M Disinfectant Wipe** [refills]. Do not reuse this container except as described. If not refilling, discard empty container in trash or recycle [if available].

{PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL}

NUGEN™ 2M Disinfectant Wipes

Active Ingredients:	
Poly(hexamethylenebiguanide) hydrochloride	0890%
Octyl decyl dimethyl ammonium chloride0.1	1333%
Dioctyl dimethyl ammonium chloride)534%
Didecyl dimethyl ammonium choride	799%
Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride 0.1	778%
[Other][Inert] Ingredients:	1666%
Total100	.0000%

KEEP OUT OF REACH OF CHILDREN

WARNING [AVISO]

See outer container for Precautionary Statements and Use directions

DISPOSAL: Dispose [wipe] [towelette] [Cloth] in trash after use. Discard empty [pouch] [packet] in trash.

EPA. Reg. No. 6836-372

EPA. Est. No. (insert EPA Est. No. here])

Net Contents: Net Weight:

[optional - wipe dimensions:] X x X [inches] [in.]

Lonza Inc. 90 Boroline Road Allendale, NJ 07401

{Optional graphic}









{Note to Reviewer: Similar representative graphics may be added for the final printed label}