



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 17, 2017

Ms. Kathryn Rosario
Regulatory Assurance Specialist for,
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: PRIA Label Amendment: To add the Viral Emerging Pathogens
language Product Name: NuGen MB5A-128
EPA Registration Number: 6836-362
Application Date: February 24, 2017
Decision Number: 526670

Dear Ms. Rosario:

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.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

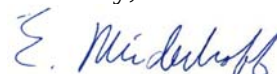
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

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 Karen M. Leavy at (703)-308-6237 or via email at Leavy.Karen@epa.gov.

Sincerely,



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

Enclosure

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 MB⁵A-128

One-Step Disinfectant

[Cleaner –Virucide* – Deodorizer]

[For Homes, Restaurants, Hospitals, Institutional and Industrial Use]

[Effective in hard water up to 250 ppm hardness (calculated as CaCO₃) in the presence of 5% serum contamination]

[Formulated for Effective Farm Premise Sanitation]

[Formulated for Effective Poultry Premise Sanitation]

[Formulated for Effective Swine Premise Sanitation]

[Formulated for Effective Mushroom Farm Sanitation]

[Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection]

[For use in federally inspected meat and poultry plants]

[• Staphylocidal • Pseudomonacidal • Bactericidal • Salmonellacidal¹ • Virucidal* • Fungicidal]

Active Ingredients:

Dioctyl dimethyl ammonium chloride.....8.06%

Alkyl (67%C₁₂, 25%C₁₄, 7%C₁₆, 1%C₁₈) dimethyl benzyl ammonium chloride5.37%

Other Ingredients:.....86.57%

Total:.....100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg. No. 6836-362

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

Net Contents (insert container size here)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode] [UPC Code] [QR Code]

Manufactured by:

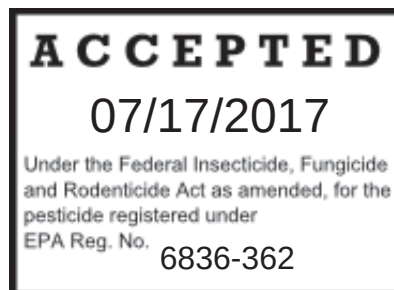
Lonza Inc., 90 Boroline Road, Allendale, NJ 07401

¹ (Salmonella enterica)

NUGEN MB⁵A-128

EPA Reg. No. 6836-362

EPA Amendment 2016-06-08 EPA Submission 02-08-2017



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. May be fatal if inhaled or absorbed through skin. Harmful if swallowed. Do not breathe vapor or spray mist. Wear appropriate protective eyewear such as goggles, face shield, or safety glasses. Wear protective clothing and protective (rubber or chemical resistant) gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

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 OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

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

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.

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

ENVIRONMENTAL HAZARDS

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

{Note to reviewer: Pages 3-9 are considered optional marketing language.}

Cleans [Cleaner]

Concentrate [Concentrated]

Deodorizes [Deodorant]

Disinfects [Disinfectant]

This product contains no [phosphates] [or] [phosphorous compounds].

Marketing Claims

- New dilutable concentrate disinfectant
- New with 5 minute contact times
- New, 5 minute disinfection

Cleaning Claims

- [all] [multi-purpose] [everyday][daily][touch-up][cleaning]
- Cleans
- Cleans [and] [disinfects] in one easy step (when used according to disinfection directions).
- Cleans what you can't see
- Cuts through tough grease [and grime].
- Delivers non-acid disinfectant and cleaning performance in an economical concentrate.
- For [quick clean-ups][in one easy step] (when used according to disinfection directions).
- [Great] For cleaning [(insert from list of any approved use site)]
- [Great] For cleaning your home [home][kitchen][bathroom][room][dorm][office][cart][car][classroom][gym]
- One step [cleaning][cleaner] [Disinfectant] (when used according to disinfection directions).
- Cleans [and disinfects] every day kitchen messes.
- Will not leave grit or soap scum.

Odor elimination claims

- Clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- Deodorizes
- Deodorizes by killing microorganisms that cause offensive odors.
- Effective against odor causing bacteria
- [Eliminates][Neutralizes] odors [and freshens]
- [Improves labor results by] effectively controls [controlling] malodors.
- 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.
- Leaves a clean fresh scent.
- Provides long lasting freshness against tough [pet] odors such as odors from litter boxes and pet accidents.
- Tough on odors

Antimicrobial claims

- [Antibacterial][Antimicrobial][Disinfects]
- Convenient 5 minute hospital disinfection
- Disinfects (insert from approved list of pathogens) in [just] 5 minutes
- 5 minute acting [disinfectant] [antimicrobial]
- Hard surface [antimicrobial][antibacterial][disinfectant]
- [improves labor results with] easy to use 5 minute hospital disinfection contact time
- is a complete, chemically balanced disinfectant [that provides clear use solutions even in the presence of hard water].
- is a [concentrated] [one-step] [Hospital Use] disinfectant cleaner that is effective against a broad spectrum of bacteria and is virucidal* [including HIV-1, the AIDS Virus and Hepatitis B Virus and Hepatitis C Virus] (when used according to disinfection directions).
- is a proven "one-step" disinfectant - cleaner - sanitizer - virucide* - fungicide which is effective in water up to 250 ppm hardness in the presence of 5% serum contamination (when used according to disinfection directions).
- is a proven "one-step" disinfectant - cleaner - virucide* which is effective in water up to 250 ppm hardness in the presence of 5% serum contamination in 5 minutes [minute contact time] (when used according to disinfection directions).
- is virucidal* [including HIV-1, the AIDS Virus and Hepatitis B Virus and Hepatitis C Virus] in 5 minute contact time
- kills Norovirus [in [just] 5 minutes]
- kills Rotavirus [in [just] 5 minutes]
- [Kills] [Eliminates] [Removes] [Destroys] [fights] (*Insert pathogen or pathogens from lists on page 8*) on [pre-cleaned] environmental surfaces [in [just] 5 minutes]
- [Kills] [Eliminates] [Removes] [Destroys] [fights][Germs] [Bacteria] [Viruses*] [and] [Fungus] [on [pre-cleaned] environmental surfaces] [in [just] 5][10] minutes] {10 minutes when claiming fungus}
- meets AOAC efficacy standards for hospital disinfectants in 5 minutes [minute contact time].
- Provides hospital disinfection [in] [in just] 5 minute[s] [contact time]
- [Kills] [Eliminates] [Removes] [Destroys] [fights] Trichophyton mentagrophytes [T. Ment.] [athlete's foot fungus]

Usages claims

- For homes, Institutional and Industrial Use
- For hard, non-porous household surfaces [all around the house] indoor and outdoor
- For use [away from home][in public places]
- Is a [versatile] disinfectant and for hard, nonporous nonfood contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- Multi-purpose
- Multi-surface

Value claims

- Helps you finish [disinfecting]
- [Is a heavy duty disinfectant cleaner that] cleans, disinfects and deodorizes in one labor saving step.
- Is an economical concentrate that can be diluted for use with [with a mop and bucket], [sponge or by soaking], [Emersion in bulk liquid] [Squirt spouts/nozzles] [Trigger sprayers], [and or] [spray floor mops].
- Is effective yet economical.
- Saves [Labor] times [with 5 minute disinfection]

Cross-contamination is of major housekeeping concern. **NUGEN MB⁵A-128** has been formulated to aid in the reduction of cross-contamination on treated surfaces not only in hospitals, but in schools, institutions and industry.

NUGEN MB⁵A-128

- as a disinfectant on hard, nonporous surfaces.
- by soaking, immersion.
- Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers and other Poultry House related equipment, and all other hard, nonporous surfaces in the Hatchery environment.
- for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- for disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces.
- for Poultry Premise disinfection [Hatcheries]: Egg Receiving Area, Egg Holding Area; Setter Room, Tray for Farm Premise disinfection of hard nonporous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- for Swine Premise disinfection: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and areas, Nursery blocks, Creep area, Chutes.
- in federally inspected Meat & Poultry Plants as a disinfectant on all surfaces in inedible product processing areas, nonprocessing areas and / or exterior areas.
- in kitchens, bathrooms and other household areas.
- in work areas such as tool rooms and garages for odor control and light duty cleaning.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps.
- [on] [to clean and disinfect] nonporous personal protective safety equipment, wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with clean, warm water [about 120°F] and allow to air dry before reuse. [Precaution: Cleaning at above 120°F temperature could overheat and distort the personal safety equipment and require equipment replacement.]
- Use of this product will control unpleasant [malodors] odors.
- to clean and disinfect finished floors. Must be applied with damp mop or autoscrubber. Cleans and disinfects without dulling gloss.
- to clean and disinfect finished floors, sinks and tubs.
- to clean and disinfect non-porous ambulance equipment and surfaces. Rinse with clean water all equipment that will come in prolonged contact with skin before reuse.
- [to clean and disinfect] nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.
- to clean and disinfect nonporous salon / barber tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- to deodorize coolers, buckets, garbage pails and other areas where strong odors may develop.
- to remove odors caused by flooding and smoke from fires.
- with a mop and bucket, sponge, squirt spouts/nozzles, trigger sprayers, spray floor mop

NUGEN MB⁵A-128 is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **NUGEN MB⁵A-128** has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings. Use of **NUGEN MB⁵A-128** must be limited to areas where compost and mushrooms are not present.

[AREAS OF USE:]

Use **NUGEN MB⁵A-128** in:

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

Bathrooms
Homes [Households]
Kitchens

Clinics
Dental offices
Health Care Facilities
Hospitals
Medical Offices
Medical Related facilities
Nursing homes
Sick Rooms
Long term care facilities

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Food processing plants
Food storage areas
Institutional kitchens
Restaurants [Front of House]
USDA inspected food processing facilities
Fish Markets
Lounges

Athletic facilities
Barber shops
Health spas
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Locker rooms
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Offices

Prisons
Public facilities
Public rest rooms,
Schools
Shower and bath areas
Salons [Beauty] [Tanning]
Universities
Theaters
Auditoriums
Churches

Camp grounds
Playground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
Mushroom Farms
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos
Veterinary Clinics

Airplanes
Airports
Ambulances
Boats
Buses
Campers
Cars
Elevators
Emergency [Police] [EMS] [Fire] [Rescue] vehicles

Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

[TYPES OF SURFACES:]

Use **NUGEN MB⁵A-128** on washable hard, nonporous surfaces of:

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

Appliances, exteriors	Tiles, glazed
Bathroom fixtures	Ultrasonic baths
Bathtubs [fiberglass]	Urinals
Cabinets	Walls
Call Buttons	Whirlpool [bathtubs] [tubs] [units]
Cages	
Chairs	Non-critical medical device surfaces:
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps	Beds [Medical] [Hospital]
Computer keyboards	Bed frames
Tablet computers	Bed rails
Conductive flooring	Crutches
Counters [Countertops]	Defibrillators
Countertop laminates	Gurneys
Desks	Non-critical [hospital] [medical] equipment surfaces:
Doorknobs	[Medical] Examining tables
Floors	[Medical] [Hospital] Lamps
Foot Spas	Rescue tools
Garbage cans	Resuscitators
Highchairs	[Medical] [Hospital] Scales
Kennel runs	Stands
Microwave ovens, exteriors	Stretchers
Outdoor [patio] furniture except cushions and wood frames	Stethoscopes
Refrigerators, exteriors	Walkers
Refrigerated storage and display equipment	Wheel chairs
Remote controls	
Showers	Other hard nonporous surfaces made of:
Shower stalls	Glazed ceramic
[Fiberglass] Shower stalls	Glazed enameled surfaces
[Fiberglass] Sinks [bathroom] [kitchen]	Glazed porcelain
Sinks [bathroom] [kitchen]	Laminated surfaces
Stoves [stovetops]	Metal
Tables, [Non-wooden picnic tables]	Plastic [such as polystyrene or polypropylene]
Telephones	Sealed stone
Mobile phones	Stainless steel
Toilets	Upholstery, vinyl and plastic
Toilet bowls	Woodwork, finished
Toilet bowl surfaces	
Toys ¹	
Tubs [Fiberglass]	

¹Rinse toys with clean, potable water after disinfecting.

[Organisms]

NUGEN MB⁵A-128 is a [one-step] [Hospital use] disinfectant, Bactericidal according to the current AOAC Use Dilution Test Method and Virucidal* according to the virucidal qualification modified in the presence of 250 ppm hard water plus 5% organic serum against:

{or}

NUGEN MB⁵A-128 is effective against:

5 MINUTE CONTACT TIME:

[Bacteria:]

Pseudomonas aeruginosa [Pseudomonas]

Salmonella enterica [Salmonella]

Staphylococcus aureus [Staph]

Acinetobacter baumannii [Acinetobacter]

Enterobacter aerogenes

Enterobacter cloacae NDM 1 – Carbapenem Resistant [CRE]

Enterococcus faecalis - Vancomycin resistant [VRE]

Escherichia coli [E. coli]

Escherichia coli O157:H7 [E. coli O157:H7]

Escherichia coli – Extended Spectrum Beta Lactamase producing [ESBL E. coli]

Escherichia coli NDM-1 - Carbapenem Resistant [CRE]

Klebsiella pneumoniae [Klebsiella]

Klebsiella pneumoniae – Extended Spectrum Beta Lactamase producing

Klebsiella pneumoniae NDM 1- Carbapenem Resistant [CRE]

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

Staphylococcus aureus - Methicillin-Resistant [MRSA]

Staphylococcus aureus - Vancomycin Resistant – [VRSA]

Streptococcus pyogenes [Strep] [a cause of scarlet fever]

[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

*Influenza A Virus (H7N9)

*Influenza A Virus / Hong Kong [Influenza] [Influenza Virus]

*Norwalk Virus – Norovirus

*Respiratory Syncytial Virus [RSV]

*SARS associated Coronavirus [SARS]

*Vaccinia Virus [Pox Virus]

[Animal Viruses:]

Avian Influenza (H5N1)

Feline Calicivirus

[Fungi:]

Candida albicans

10 MINUTE CONTACT TIME:

[Fungi:]

Trichophyton mentagrophytes [athlete's foot fungus] [4 oz. per gallon]

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are 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).

NUGEN MB⁵A-128

EPA Reg. No. 6836-362

EPA Amendment 2016-06-08 EPA Submission 02-08-2017

- Kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 Influenza A virus.

[NUGEN MB⁵A-128] [Brand Name] [This Product] [Is for]:

- Use [clean] solution for [up to] [7 days] [14 days] [1 week] [2 weeks] when stored in a sealed [spray] container
- [Use solution] [clean solution] effective for [up to] [7 days] [14 days] [1 week] [2 weeks] when stored in a sealed [spray] container
- [Use] [clean] solution can be used [up to] [7 days] [14 days] [1 week] [2 weeks] after dilution when stored in a sealed [spray] container

Emerging Viral Pathogen Claims

{Note to Reviewer: These statements for claims against large non-enveloped, and/or enveloped emerging viral pathogens shall not appear on marketed (final print) product labels.}

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"

NUGEN MB⁵A-128 meets the criteria for use against the following categories of emerging viral pathogens when used according to the Norovirus use directions on hard, non-porous surfaces:

- Enveloped viruses
- Large, non-enveloped viruses

NUGEN MB⁵A-128 has demonstrated effectiveness against viruses similar to *[name of emerging virus]* on hard, non-porous surfaces. Therefore, **NUGEN MB⁵A-128** can be used against *[name of emerging virus]* when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the *[CDC or OIE]* website at *[pathogen-specific website address]* for additional information.

[Name of illness/outbreak] is caused by *[name of emerging virus]*. **NUGEN MB⁵A-128** kills similar viruses and therefore can be used against *[name of emerging virus]* when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the *[CDC or OIE]* website at *[website address]* for additional information.

Dilution:

Disinfection [1:128]1 oz. per gallon of water [1049 ppm active]
Disinfection [1:64]2 oz. per gallon of water [2098 ppm active]
Disinfection [1:32]4 oz. per gallon of water [4196 ppm active]

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

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

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.

Preparation of Disinfectant Use-Solution:

[Add] [mix] [1 oz. per gallon of water] [1:128] or [1 - 2 oz. per gallon of water] or [1 - 4 oz. per gallon of water].
For [heavy duty use] [fungicidal activity against Trichophyton mentagrophytes], add [mix] 4 oz. per gallon of water [1:32]. [Use 4 oz. per gallon of water to kill Trichophyton mentagrophytes [athlete's foot fungus].]

DISINFECTION / VIRUCIDAL:

Apply use-solution to hard, nonporous surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Treated surfaces must remain wet for 5 minutes. Wipe dry with a cloth, sponge or mop or allow to air dry. For heavily soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface; rub with a brush, sponge or cloth. Do not breathe spray.

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

To disinfect food processing facilities: Spray surfaces with solution and allow to remain wet for 5 minutes. Rinse food contact surfaces with potable water prior to reuse.

NUGEN MB⁵A-128 is effective in one step against *Candida albicans* at 1 oz. per gallon in 250 ppm hard water and 5% serum. Treated surfaces must remain wet for 5 minute contact time.

NUGEN MB⁵A-128 is effective in one step against *Trichophyton mentagrophytes* [athlete's foot fungus] at 4 oz. per gallon in 250 ppm hard water and 5% serum. Treated surfaces must remain wet for 10 minute contact time.

{Note to reviewer: Only one of the following two statements will be used.}

Bactericidal Stability of Spray Use-Dilution: [Tests confirm that] the use solution of this product, when stored in a sealed container such as a spray bottle, remains effective for [up to 7 days] [for up to 14 days] [for up to one week] [2 weeks] [at the indicated bacterial contact time]. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product.

{or}

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

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

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood

barrier or otherwise enter normally sterile areas of the body. [This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection].
{or}

This product is not for use on medical device surfaces.

***KILLS HIV AND HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS**

PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS] or Hepatitis B Virus [HBV] or Hepatitis C Virus [HCV].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV OR HCV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

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

Cleaning Procedure: Blood and other body fluids containing HIV-1 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **NUGEN MB⁵A-128**.

Contact Time: Leave surface wet for 5 minutes with a [1 oz.] or [1 - 2 oz.] or [1 - 4 oz.] per gallon use-solution.

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

NON-ACID TOILET BOWL [AND URINAL] DISINFECTANT / CLEANER DIRECTIONS:

Remove gross filth prior to disinfection.

From Concentrate:

Add 1 oz. to the bowl and mix. Brush over exposed surfaces and under the rim; allow to stand for 5 minutes and flush.

From Use Solution:

Empty toilet bowl [or urinal] and apply 1 oz. per gallon use-solution to exposed surfaces and under the rim with a cloth, mop, sponge or mechanical spray. Brush or swab thoroughly; allow to stand for 5 minutes and flush.

For Heavy Duty Use:

Empty toilet bowl [or urinal] and apply 4 oz. per gallon use-solution to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer, brush or swab thoroughly; allow to stand for 5 minutes and flush.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use **NUGEN MB⁵A-128** at [1 oz. per gallon] or [1 - 2 oz. per gallon]. Apply with a damp mop, spray mop [system] or auto scrubber or spray. Allow surface to remain wet for 5 minutes. Wipe or allow to air dry.

SALON / BARBER INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] / VIRUCIDE DIRECTIONS:

Mix [1 oz.] or [1 - 4 oz.] of **NUGEN MB⁵A-128** per gallon of water [[1 oz.] or [1- 2 oz.] of **NUGEN MB⁵A-128** per 4 quarts of water] to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and allow them remain to wet for contact time indicated on the label. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after required contact time, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

ULTRASONIC BATH DISINFECTANT / VIRUCIDAL DIRECTIONS:

Use **NUGEN MB⁵A-128** to disinfect hard nonporous, non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1 oz. per gallon of water directly into bath chamber. Preclean heavily soiled objects. Place objects into unit and operate for a minimum of 5 minutes, according to the manufacturer's directions. Remove objects and wash with sterile water [sterile water for injection] or allow to air dry. Prepare fresh solution for each use.

DISINFECTION OF [WHIRLPOOL [UNITS] [BATH[S]]:

After using the [whirlpool [unit] [bath]], drain and refill with fresh water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet]. Add 1 oz. of **NUGEN MB⁵A-128** for each gallon of fresh water added. Start the pump to circulate the solution. Wash down the sides, [[deck,] [seat of chair lift,] [any related equipment,]] and any uncovered surfaces on the [bath] [unit] with a clean swab, brush or sponge. Treated surfaces must remain wet for a minimum of 5 minutes. After the [unit] [bath] has been thoroughly disinfected, drain the solution from the [unit] [bath] and rinse the disinfected surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.

DISINFECTION OF FOOT SPAS:

After using the whirlpool foot spa, drain the water. Use 1 oz. of product per gallon of water to cover the intake valve or 2 inches above the highest jet. Start the pump to circulate the solution. Swab exposed surfaces including unit sides, chair and any related equipment thoroughly with a cloth, sponge or brush and allow treated surfaces and solution to stand for a minimum of 5 minutes. After the unit has been thoroughly disinfected rinse all disinfected surfaces with fresh water.

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

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 oz. of **NUGEN MB⁵A-128** per gallon of water [or equivalent dilution] for a period of 5 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate all surfaces with a use-solution of 1 oz. of **NUGEN MB⁵A-128** per gallon of water [or equivalent dilution] for a period of 5 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

POULTRY AND SWINE PREMISE DISINFECTION / VIRUCIDAL DIRECTIONS:

Remove all animals and feeds from premises, vehicles and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1 oz. of **NUGEN MB⁵A-128** per gallon of water. Saturate surfaces with the disinfecting solution for 5 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

HATCHERIES: Use [1 oz.] or [1 - 2 oz.] or [1 - 4 oz.] **NUGEN MB⁵A-128** per gallon of water to treat the following hard nonporous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Leave all treated surfaces wet for 5 minutes. Then allow to air dry.

VEHICLES: Treat all vehicles including mats, crates, cabs and wheels with water **NUGEN MB⁵A-128**. Use [1 oz.] or [1 - 2 oz.] or [1 - 4 oz.] of **NUGEN MB⁵A-128** per gallon of water to treat all vehicles. Leave all treated surfaces wet for contact time indicated on the label; allow to air dry.

DRESSING PLANT DISINFECTANT DIRECTIONS: Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect all rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Saturate all surfaces with a [1 oz.] or [1 - 2 oz.] or [1 - 4 oz.] of **NUGEN MB⁵A-128** per gallon of water solution. Scrub to loosen all soils. Surfaces must remain wet for 5 minutes, then thoroughly rinsed with potable water before operations are resumed.

MUSHROOM FARM PREMISE USE:

Site Preparation: The first step in any on-going sanitation program must be the removal of gross contamination and debris. This may be accomplished by using a shovel, broom, or vacuum, depending on the area to be disinfected.

Cleaning and Disinfection: For general cleaning and disinfection, use [1 oz.] or [1 - 2 oz.] or [1 - 4 oz.] of **NUGEN MB⁵A-128** per gallon of water [or equivalent dilution]. Apply use solution using a sprayer to thoroughly wet the surfaces. Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must be allowed to remain wet for 5 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first.

For Heavy Duty Cleaning: When greater cleaning is desired, use 1 oz. of **NUGEN MB⁵A-128** per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

DO NOT APPLY USE-SOLUTION TO THE MUSHROOM CROP, COMPOST OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.

SEWER BACKUP AND RIVER FLOODING: During mitigation procedures, dilute 1 - 2 oz. of the concentrate per gallon of water, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

TO CLEAN AND DEODORIZE: Mix 1 oz. [of **NUGEN MB⁵A-128** per gallon of water or [1 - 2 per gallon] or [1 - 4 oz. per gallon] to clean and deodorize surfaces. Apply using a sprayer. Wipe or allow to air dry.

DEODORIZING DIRECTIONS:

SPRAY MOPPING SOLUTIONS: 1 - 2 oz. per gallon of water eliminates undesirable odors. Allow surfaces to air dry.

NURSING HOMES, HOSPITALS, HOTELS, SCHOOLS, RESTAURANTS: Using [1 - 2 oz.] or [1 - 4 oz.] in chemical toilets, waste receptacles, bed pans, drainage bottles, diaper pails, hampers, disposals, commodes and air conditioner pans will eliminate odors.

MOPPING SOLUTIONS, AUTOMATIC SCRUBBERS: Use [1 - 2 oz. per gallon] or [1 - 4 oz.] per gallon of cleaning solution eliminates undesirable odors.

AIR FRESHENER/AUTOMOTIVE USES: 4 ounces per gallon of water or desired concentration is effective on smoking and cooking odors (garlic, fish, onions, etc.). Automobile odors from tobacco, musty carpet smell and beverage smells will be eliminated.

RV HOLDING TANKS: Toilet waste: cover bottom of holding tank with water and add [1 - 2 oz.] or [1 - 4 oz.] If odors return before time to empty, simply add [1 - 2 oz.] or [1 - 4 oz.] to the tank. Kitchen waste: [1 - 2 oz.] or [1 - 4 oz.] of **NUGEN MB⁵A-128** to gray water tank as needed to control malodors created by dirty dish water.

SEWAGE BACKUP, WATER DAMAGE: 2 - 4 oz. per gallon of water or desired concentration. Spray over affected areas before and after cleaning and extraction. Allow 5 minutes contact time. Use proper ventilation; open windows.

CLEANING SOLUTION: Dilute 1 - 2 oz. per gallon of water for cleaning of, tables, walls, bathrooms, toilet seats, mopping floors and large routine applications. Apply to surfaces using trigger spray or other spray device. Remove excess liquid or allow surfaces to air dry.

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

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

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 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 C3 of the Label Review Manual's statements about burning are labeled as "Not required;" 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 $\frac{1}{4}$ 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.

[Metal containers only:] DO NOT cut or weld metal containers.

[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: Several packaging options are designed for use dilution systems with sealed containers or bottles 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.

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.

{PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL}

FOR DISINFECTION

Note to reviewer: the following will be used for 1/4 oz. of concentrate:
MIX EACH PACKET WITH [1 QUART] OF WATER

Note to reviewer: the following will be used for 1 oz. of concentrate:
MIX EACH PACKET WITH [1 GALLONS] OF WATER

Note to reviewer: the following will be used for 2 oz. of concentrate:
MIX EACH PACKET WITH [2 GALLONS] OF WATER

Note to reviewer: the following will be used for 4 oz. of concentrate:
MIX EACH PACKET WITH [4 GALLONS] OF WATER

{If other packet sizes are desired, new packet label will be identical and the only things that will vary are the net contents, amount of water to dilute with and ppm active quat. Those 3 items will have to match or be equivalent to the dilution chart that is shown on page 10.}

NUGEN MB⁵A-128

Active Ingredients:

Diocetyl dimethyl ammonium chloride.....	8.06%
Alkyl (67%C ₁₂ , 25%C ₁₄ , 7%C ₁₆ , 1%C ₁₈) dimethyl benzyl ammonium chloride	5.37%
Other Ingredients:	86.57%
Total:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See outer container for Precautionary Statements and Use directions

Disposal: Nonrefillable container. Do not reuse packet. Wrap and put in trash.

EPA Reg. No. 6836-xxx
EPA Est. No. (as indicated on container)
Net Contents: (insert container size here)

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

{Note to reviewer: The following is considered optional graphics and marketing language.}

{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}

[Any Kosher Symbol such as:]



[Kosher]