

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 9, 2020

Jennifer DePietro Regulatory Assurance Specialist Lonza, LLC 412 Mount Kemble Avenue, Suite 200S Morristown, NJ 07960

Subject: PRIA Label Amendment – Add efficacy claims and modify other label language

Product Name: NUGEN MB5N-64 EPA Registration Number: 6836-366 Application Date: November 6, 2020

Decision Number: 567703

Dear Ms. DePietro:

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) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

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

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with FIFRA section 6. If you have any questions, you may contact Joseph Daniels at (703) 347-8669 or via email at Daniels.joseph@epa.gov.

Eric Miederhoff
Product Manager 31
Pagulatary Managerma

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® MB5N-64

Active Ingredients:	
Dioctyl Dimethyl Ammonium Chloride	5.26%
Alkyl (C ₁₂ , 67%; C ₁₄ , 25%; C ₁₆ , 7%; C ₁₈ , 1%) dimethyl benzyl ammonium chloride	3.51%
Other Ingredients:	
Total:	100.00%

DANGER [PELIGRO]

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

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 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.

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.

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

Have the product container or label with you when calling poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

EPA Reg. No. 6836-366 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, LLC 412 Mount Kemble Avenue, Suite 200S Morristown, NJ 07960

ACCEPTED

11/09/2020

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

6836-366

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 the skin. Harmful if swallowed. Wear protective eyewear (goggles, face shield or safety glasses), 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.

{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.}

One-Step Disinfectant¹

[Cleaner¹ –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]

[Staphylocidal² • Pseudomonacidal³ • Bactericidal • Salmonellacidal⁴ • Virucidal*• Fungicidal]

Cleans [Cleaner]

Concentrate [Concentrated]

Deodorizes [Deodorant]

Disinfects [Disinfectant]

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

Marketing Claims

- Dilutable concentrate disinfectant
- 5 minute disinfection⁵
- [With] 5 minute⁵ contact times

Cleaning Claims

- [all] [multi-purpose] [everyday][daily][touch-up][cleaning¹]
- Cleans¹
- Cleans¹ [and] [disinfects¹] in one easy step (when used according to disinfection directions).
- Cleans¹ what you can't see
- Cuts through tough grease [and grime]¹.
- Delivers non-acid disinfectant and cleaning performance in an economical concentrate¹.
- For [quick clean-ups][in one easy step] (when used according to disinfection directions)¹.
- [Great] For cleaning¹ [(insert from list of any approved use site)]
- [Great] For cleaning¹ your home [home][kitchen][bathroom][room][dorm][office][cart][cart][classroom][gym]
- One-step [cleaning¹][cleaner¹] [Disinfectant¹] (when used according to disinfection directions).
- [Cleans [and disinfects] every day kitchen messes¹.
- Will not leave grit or soap scum.

Odor elimination claims

- Clean and deodorize surfaces¹ 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.

NUGEN[®] MB⁵N-64 EPA Reg. No. 6836-366 EPA Submission 2020-11-09

Odor elimination claims (cont.):

- 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 minute⁵ hospital disinfection
- Disinfects (insert from approved list of pathogens) in [just] 5 minutes⁵
- 5 minute⁵ acting [disinfectant] [antimicrobial]
- Hard, non-porous, non-food contact surface [antimicrobial][antibacterial][disinfectant]
- [improves labor results with] easy to use 5 minute⁵ 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] disinfectant¹ cleaner¹ 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" disinfectant¹ cleaner¹ 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" disinfectant¹ cleaner¹ virucide* which is effective in water up to 250 ppm hardness in the presence of 5% serum contamination in 5 minutes⁵ [minute contact time⁵] (when used according to disinfection directions).
- is virucidal* [including HIV-1, the AIDS Virus and Hepatitis B Virus and Hepatitis C Virus] in 5 minute⁵ contact time
- kills Norovirus [in [just] 5 minutes]
- [Kills] [Eliminates 99.9%] [Removes] [Destroys] [fights] (*Insert pathogen or pathogens from list on page 8*) on [pre-cleaned] environmental surfaces [in [just] 5 minutes⁵]
- [Kills] [Eliminates 99.9%] [Removes] [Destroys] [fights] [Germs] [Bacteria] [Viruses*] [and] [Fungus] [on [precleaned] environmental surfaces] [in [just] [5][10] minutes] {10 minutes when claiming fungus}
- Provides hospital disinfection [in] [in just] 5 minute⁵ [s⁵] [contact time]
- [Kills] [Eliminates 99.9%] [Removes] [Destroys] [fights] Trichophyton interdigitale [athlete's foot fungus]
- [Kills] [and] [inactivates] Candida auris on hard, non-porous surfaces
- Kills a minimum of [99.999%] [five logs] of Candida auris on hard, non-porous surfaces
- Tested according to the AOAC Use-Dilution Method for a 5 minute⁵ contact time

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, non-porous, non-food contact surfaces in Veterinarian, Animal care and Farm Premise applications.
- Multi-purpose
- Multi-surface

Value claims

- Helps you finish [disinfecting]
- Is an economical concentrate that can be diluted for use 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 and economical.
- Saves [Labor] time [with 5 minute⁵ disinfection]

Cross-contamination is of major housekeeping concern. **NUGEN[®] MB⁵N-64** has been formulated to aid in the reduction of cross-contamination on treated surfaces not only in hospitals, but in schools, institutions and industry.

Use NUGEN® MB5N-64

- as a disinfectant on hard, non-porous, non-food contact surfaces.
- by soaking, immersion in bulk liquid.
- 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, non-porous surfaces.
- for Farm Premise disinfection of hard, non-porous surfaces: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other non-porous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- for Poultry Premise disinfection [in] [Hatcheries]: Egg Receiving Area, Egg Holding Area; Setter Room, Tray 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, non-porous surfaces in the Hatchery environment.
- 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 cleaning¹.
- [on] [to clean and disinfect] non-porous 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 warm water 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.]
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps⁶.
- 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] non-porous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.
- to clean and disinfect non-porous 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® **MB**⁵**N-64** is a phosphate free, germicidal detergent effective on hard, non-porous surfaces found at mushroom farms. **NUGEN**® **MB**⁵**N-64** 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**® **MB**⁵**N-64** must be limited to areas where compost and mushrooms are not present.

[AREAS OF USE:]

Use **NUGEN® MB⁵N-64** on non-food contact surfaces 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

Hotels

Offices

Institutional facilities

Institutions Locker rooms Motels

Factories

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[®] MB⁵N-64 on washable hard, non-porous, non-food contact 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 Bathroom fixtures Bathtubs [fiberglass]

Cabinets
Call Buttons
Cages
Chairs

Coils and drain pans of air conditioning and refrigeration equipment and heat pumps

Computer keyboards
Tablet computers
Conductive flooring
Counters [Countertops]
Countertop laminates

Desks
Doorknobs
Floors
Foot Spas
Garbage cans
Highchairs
Kennel runs

Microwave ovens, exteriors

Outdoor [patio] furniture except cushions and wood

frames

Refrigerators, exteriors

Refrigerated storage and display equipment⁶

Remote controls

Showers Shower stalls

[Fiberglass] Shower stalls

[Fiberglass] Sinks [bathroom] [kitchen]

Sinks [bathroom] [kitchen] Stoves⁶ [stovetops⁶]

Tables, [Non-wooden picnic tables]

Telephones Mobile phones

Toilets
Toilet bowls

Toilet bowl surfaces

Toys⁷

Tubs [Fiberglass]

Tiles, glazed Ultrasonic baths

Urinals Walls

Whirlpool [bathtubs] [tubs] [units]

Non-critical medical device surfaces:

Beds [Medical] [Hospital]

Bed frames Bed rails Crutches Defibrillators Gurneys

Non-critical [hospital] [medical] equipment surfaces:

[Medical] Examining tables [Medical] [Hospital] Lamps

Rescue tools Resuscitators

[Medical] [Hospital] Scales

Stands Stretchers Stethoscopes Walkers Wheel chairs

Other hard, non-porous surfaces made of:

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain Laminated surfaces

Metal

Plastic [such as polystyrene or polypropylene]

Sealed stone Stainless steel

Upholstery, vinyl and plastic

Woodwork, finished

[Organisms]

NUGEN® **MB**⁵**N-64** is a [one-step] [Hospital use] disinfectant¹, 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:

NUGEN® MB⁵N-64 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

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- Carbapenum 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]

[Viruses:]

- *Adenovirus Type 5
- *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 / H3N2 [Influenza] [Influenza Virus]
- *Norwalk Virus Norovirus
- *Respiratory Syncytial Virus [RSV]
- *SARS associated Coronavirus [SARS]
- *Vaccinia

[Animal Viruses:]

*Avian Influenza (H5N1)

*Feline Calicivirus

[Fungi:]

Candida albicans

10 MINUTE CONTACT TIME:

[Fungi:]

Candida auris [16 oz. concentrate diluted with water to 1 gallon of disinfectant solution]

Trichophyton interdigitale [athlete's foot fungus] [8 oz. concentrate diluted with water to 1 gallon of disinfectant solution]

[Animal Viruses:]

Canine Parvovirus [16 oz. concentrate diluted with water to 1 gallon of disinfectant solution]

[NUGEN® MB5N-64] [Brand Name] [This Product] [Is for]:

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

{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.}

EMERGING VIRAL PATHOGEN CLAIMS

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped viruses
- Large, non-enveloped viruses

For an emerging viral pathogen	follow the directions for use for the following
that is a/an	organisms on the label:
Enveloped virus	Norovirus (tested as Feline Calicivirus)
Large, non-enveloped viruses	Norovirus (tested as Feline Calicivirus)

[NUGEN® MB⁵N-64] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [NUGEN® MB⁵N-64] 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. OR

[Name of illness/outbreak] is caused by [name of emerging virus]. [NUGEN® MB⁵N-64] 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 [1:64	4]2 oz. per gallon of water [1370 ppm active]
Disinfection [1:3]	1]4 oz. diluted with water to 1 gallon [2740 ppm active]
-	5]8 oz. diluted with water to 1 gallon [5480 ppm active]
Disinfection [1:7]	16 oz. diluted with water to 1 gallon [10960 ppm active]

*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}*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] [2 oz. per gallon of water] [1:64] or [2 - 4 oz. per gallon of use-solution] or [2 - 8 oz. per gallon of use-solution]. [For [heavy duty use] [fungicidal activity against Trichophyton interdigitale dilute 8 oz. of the concentrate with water to make 1 gallon of the use-solution [1:15].] [To kill Trichopyton interdigitale [athlete's foot fungus], dilute 8 oz. of the concentrate with water to make 1 gallon of the use-solution.] [For fungicidal activity against Candida auris, dilute 16 oz. of the concentrate with water to make 1 gallon of use-solution [1:7].] [To kill Candida auris, dilute 16 oz. of the concentrate with water to make 1 gallon of use-solution [1:7].] [To kill Canine Parvovirus, dilute 16 oz. of the concentrate with water to make 1 gallon of use-solution [1:7].]

DISINFECTION / VIRUCIDAL / FUNGICIDAL:

Apply use-solution to hard, non-porous, non-food contact surfaces, thoroughly wetting surfaces with a cloth, mop, sponge, sprayer or by immersion. Treated surfaces must remain visibly wet for 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. Wipe dry with a cloth, sponge or mop or allow to air dry. For visibly soiled areas, a preliminary cleaning is required.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from the surface. 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.

Special Instructions for Cleaning Prior to Disinfection against Candida auris

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, or eye covering. **Cleaning Procedure**: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the product. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

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

{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 as a disinfectant for {Note to reviewer: one of the following timeframes must be selected:} [up to] [7 days] [14 days] [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. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

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**® **MB**⁵**N-64**.

Contact Time: Leave surface visibly wet for 5 minutes with a [2 oz.] or [2 - 4 oz.] or [2 - 8 oz.] per gallon use-solution.

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

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

Remove gross filth prior to disinfection.

From Concentrate:

Add 2 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 2 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 8 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**[®] **MB**⁵**N-64** at [2 oz.] *or* [2 - 4 oz.] per gallon of use-solution. Apply with a damp mop, spray mop [system] or auto scrubber or spray. Allow surface to remain visibly wet for 5 minutes. Wipe or allow to air dry.

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

Mix [2 oz.] or [2 - 8 oz.] of **NUGEN**® **MB**⁵**N-64** per gallon of use-solution [[2 oz.] or [2 - 4 oz.] of **NUGEN**® **MB**⁵**N-64** per 4 quarts of use-solution] to disinfect hard, non-porous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and allow them to remain visibly wet for contact time indicated on the label. For visibly 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**® **MB**⁵**N-64** to disinfect hard, non-porous, non-critical objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 2 oz. per gallon of water directly into bath chamber. Preclean visibly 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 2 oz. of **NUGEN® MB⁵N-64** 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 visibly 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 visibly soiled units.

DISINFECTION OF FOOT SPAS:

After using the whirlpool foot spa, drain the water. Use 2 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, non-porous 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. Using the appropriate dilution, saturate surfaces with a use-solution of NUGEN® MB5N-64 for a period of 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. 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. Using the appropriate dilution, saturate all surfaces with a use-solution of **NUGEN® MB⁵N-64** for a period of 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. 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. Using the appropriate dilution of **NUGEN® MB⁵N-64**, saturate surfaces with the disinfecting solution for 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. 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 [2 oz.] or [2 - 4 oz.] or [2 - 8 oz.] or [2 - 16 oz.] of **NUGEN**[®] **MB**⁵**N-64** per gallon of use-solution to treat the following hard, non-porous surfaces: hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard, non-porous surfaces. Leave all treated surfaces visibly wet for 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. Then allow to air dry. Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed.

VEHICLES: Treat all vehicles including mats, crates, cabs and wheels with water and **NUGEN[®] MB⁵N-64**. Use [2 oz.] *or* [2 - 4 oz.] *or* [2 - 8 oz.] of **NUGEN[®] MB⁵N-64** per gallon of use-solution to treat all vehicles. Leave all treated surfaces visibly 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 visible soils prior to application. Saturate all surfaces with a [2 oz.] or [2 - 4 oz.] or [2 - 8 oz.] of **NUGEN® MB⁵N-64** per gallon of use-solution. Scrub to loosen all soils. Surfaces must remain visibly wet for 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]], 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 [2 oz.] or [2 - 4 oz.] or [2 - 8 oz.] of **NUGEN® MB⁵N-64** per gallon of use-solution. 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 visibly wet for 5 minutes [10 minutes for [Trichophyton interdigitale] [and] [Candida auris] [and] [Canine Parvovirus]]. Wipe or allow to air dry. For visibly soiled areas, preclean first. **For Heavy Duty Cleaning:** When greater cleaning is desired, use 4 oz. of **NUGEN® MB⁵N-64** per gallon of use-solution. Visibly 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.

WATER DAMAGE RESTORATION AGAINST ODOR-CAUSING BACTERIA FOR HOME AND INDUSTRIAL USE: {NOT FOR USE IN CALIFORNIA}

This product is particularly suitable for use in water damage restoration situations against odor causing bacteria on the following porous and semi-porous materials: carpets, carpet cushions, subfloors, drywall, trim and frame lumber, tackless strip and paneling. Using appropriate dilution, saturate the affected materials with enough product to remain visibly wet for at least 5 minutes.

Sewer Backup and River Flooding: During mitigation procedures, dilute 2 - 4 oz. of the concentrate per gallon of use-solution, allowing for the diluting effect of absorbed water within saturated materials. Remove visible soil along with non-salvageable materials. Saturate all affected areas with a coarse spray device before and after cleaning and extraction.

Carpets, Carpet Cushions and Other Porous Materials such as Subfloors, Drywall, Trim and Frame Lumber, Tackless Strip and Paneling: For water damage from a clean source, extract excess water. Test hidden area for colorfastness. Dilute 2 - 4 oz. of the concentrate per gallon of use-solution, allowing for the diluting effect of absorbed water within saturated materials. Remove gross filth or heavy soil. Saturate all affected areas with a coarse spray device. Roll, brush or agitate into the materials and allow materials to remain visibly wet for 5 minutes. Follow with a thorough extraction. Dry rapidly and thoroughly.

TO CLEAN AND DEODORIZE: Mix [2 oz.] or [2 - 4] or [2 - 8 oz.] of **NUGEN[®] MB⁵N-64** per gallon of use-solution to clean and deodorize surfaces. Apply using a sprayer. Wipe or allow to air dry.

DEODORIZING DIRECTIONS:

Spray Mopping Solutions: 2 - 4 oz. per gallon of use-solution eliminates undesirable odors. Allow surfaces to air dry.

Nursing Homes, Hospitals, Hotels, Schools, Restaurants: Using [2 - 4 oz.] *or* [2 - 8 oz.] per gallon of use-solution 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 [2 - 4 oz.] *or* [2 - 8 oz.] per gallon of cleaning solution to eliminate undesirable odors.

Air Freshener/Automotive Uses: 8 ounces per gallon of use-solution 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. Dilute [2 - 4 oz.] or [2 - 8 oz.] of **NUGEN**[®] **MB**⁵**N-64** per gallon of use-solution, and pour it into holding tank. If odors return before time to empty, simply dilute [2 - 4 oz.] or [2 - 8 oz.] of **NUGEN**[®] **MB**⁵**N-64** per gallon of use-solution, and add it to the tank. Kitchen waste: Dilute [2 - 4 oz.] or [2 - 8 oz.] of **NUGEN**[®] **MB**⁵**N-64** per gallon of use-solution, and add to gray water tank as needed to control malodors created by dirty dish water.

Pet Odors: Use 8 - 12 oz. per gallon of use-solution, or desired concentration, for urine, feces, and vomit, in carpet and upholstery. Clean prior to application then spray onto affected areas. Test hidden area for colorfastness. Allow 5 minutes contact time. Then blot with clean cloth. Allow to dry. Also effective on pet bedding and litter boxes.

Sewage Backup, Water Damage: 4 - 8 oz. per gallon of use-solution 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 2 - 4 oz. per gallon of use-solution for cleaning of kitchen counters, 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.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Open dumping is prohibited. Store in original container in areas inaccessible to children. **Pesticide Disposal:**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. *{Plastic and Metal Containers:}* Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{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.

NUGEN[®] MB⁵N-64 EPA Reg. No. 6836-366 EPA Submission 2020-11-09

¹On hard, non-porous, non-food surfaces

² Staphylococcus aureus

³ Pseudomonas aeruginosa

⁴ Salmonella enterica

⁵ 10-minute contact time for Trichophyton interdigitale and Candida auris

⁶ Allow the surface to adjust to room temperature before disinfection.

⁷ Rinse toys with clean, potable water after disinfecting.

{PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL}

FOR DISINFECTION

Note to reviewer: the following will be used for ½ oz. of concentrate: MIX EACH PACKET WITH 1 QUART OF WATER

Note to reviewer: the following will be used for 4 oz. of concentrate: MIX EACH PACKET WITH 2 GALLONS OF WATER

Note to reviewer: the following will be used for 8 oz. of concentrate: MIX EACH PACKET WITH 4 GALLONS OF WATER

Note to reviewer: the following will be used for 16 oz. of concentrate MIX EACH PACKET WITH 8 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® MB5N-64

Active ingredients:	
Dioctyl Dimethyl Ammonium Chloride	5.26%
Alkyl (C12, 67%; C14, 25%; C16, 7%; C18, 1%) dimethyl benzyl ammonium chloride	3.51%
Other Ingredients:	
Total:	

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. 6836-366

Active Ingredientes

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

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

SECONDARY CONTAINER LABEL

{Note to reviewer: When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements:}

NUGEN® MB5N-64

Active Ingredients:	
Dioctyl Dimethyl Ammonium Chloride	5.26%
Alkyl (C ₁₂ , 67%; C ₁₄ , 25%; C ₁₆ , 7%; C ₁₈ , 1%) dimethyl benzyl ammonium chloride	
Other Ingredients:	91.23%
Total:	

The product in this container must be diluted at the use rate of 2 oz. or less per gallon of water as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN DANGER [PELIGRO]

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Causes substantial but temporary eye injury. Do not get in eyes, on skin, or on clothing. Wear protective eyewear such as goggles, face shield, or safety glasses and waterproof 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 OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

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

Follow the directions for use on the pesticide label when applying this product.

EPA Reg. No. 6836-366

Diluted product not for sale or distribution.

{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]