



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 6, 2019

Ms. Christina Swick
Regulatory Agent for,
c/o Lonza, Inc.
412 Mt. Kemble Ave., Suite 200S
Morristown, NJ 07960

Subject: Notification per PRN 98-10 – Add the registered trademark symbol to the labeling
Product Name: NuGEN[®]™ MB⁵A Concentrate
EPA Registration Number: 6836-370
Application Date: April 22, 2019
Decision Number: 550565

Dear Ms. Swick:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

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If you have any questions, you may contact Karen M. Leavy at (703)-308-6237 or via email at Leavy.Karen@epa.gov.

Sincerely,

A handwritten signature in black ink that reads "Karen M. Leavy, Esq.". The signature is written in a cursive style with a large initial "K" and a long, sweeping underline.

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

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 Concentrate

FOR MANUFACTURING-USE ONLY

Active Ingredients:

Dioctyl Dimethyl Ammonium Chloride	33.76%
Alkyl (C ₁₂ 67% C ₁₄ 25% C ₁₆ 7% C ₁₈ 1%) Dimethyl Benzyl Ammonium Chloride	22.51%
Other Ingredients:	43.73%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg. No. 6836-370

EPA Est. No. (as indicated on container)

Net Contents: (insert container size here)

[DOT symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[BARCODE]

Manufactured by:

Lonza Inc.

412 Mt. Kemble Ave., Suite 200S

Morristown, NJ 07960

NOTIFICATION

6836-370

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/06/2019

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. Wear goggles or face shield, protective clothing and rubber gloves. May be fatal if absorbed through the skin or inhaled. May be fatal if swallowed. Do not breathe spray mist (or vapor). Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N₁, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N₁, R, or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco or using the toilet. Remove contaminated clothing and wash 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 the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferable by mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

PHYSICAL OR CHEMICAL HAZARDS

DO NOT USE OR STORE NEAR HEAT OR FLAME

ENVIRONMENTAL HAZARDS

{If container size is 5 gallons or greater, use the following statement}

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.

DIRECTIONS FOR USE

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

For formulation or repackaging into antimicrobial products for use in medical, commercial, industrial, institutional, and home premises.

Formulated or repackaged products must be registered with the EPA. Formulators using this product are responsible for providing data for the EPA registration of their formulated product.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE

Do not store on side. Avoid creasing or impacting of side walls.

PESTICIDE DISPOSAL

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

CONTAINER HANDLING

(For Nonrefillable Plastic containers \leq 5 gallons)

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For Nonrefillable Plastic containers $>$ 5 gallons but \leq 100 gallons)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple Rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For Nonrefillable Containers $>$ 100 gallons)

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. To clean the container, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water; . Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to point of sale or offer for recycling if available or reconditioning if appropriate.

Nugen™ is a trademark of Lonza or its affiliates