

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 29, 2016

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

Subject: Label Amendment – Revision of precautionary statement

Product Name: NUGEN MB⁵A Concentrate

EPA Registration Number: 6836-370 Application Date: August 30, 2016

Decision Number: 521331

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.

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

Page 2 of 2 EPA Reg. No. 6836-370 Decision No. 521331

with FIFRA section 6. If you have any questions, please contact Tara Flint at flint.tara@epa.gov or Eric Miederhoff at Miederhoff.eric@epa.gov

Sincerely,

Enic Miederhoff

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 Concentrate

FOR MANUFACTURING-USE ONLY

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. 90 Boroline Road Allendale, NJ 07401 ACCEPTED

09/29/2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 2000

6836-370

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 NIOSH approved particulate respirator with any N, R, P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. 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.

{Note to reviewer: For Nonrefillable Plastic drums}

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 DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Triple rinse (or equivalent). Then offer for recycling or reconditioning, 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.

{Note to reviewer: For Nonrefillable Totes}

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 DISPOSAL

Nonrefillable container. Do not reuse or refill this container. Empty tote container must be returned to a tote collection agent.

Residue Removal – Cleaning container before final disposal is the responsibility of the person disposing of the container. To clean container before final disposal, fill container about 10 percent full with water; agitate container vigorously; discard rinsate according to pesticide disposal instructions; repeat this rinsing procedure two more times. For additional container disposal information, contact product supplier.

Nugen[™] is a trademark of Lonza or its affiliates