

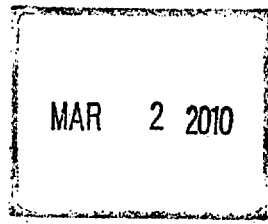
6836-181

3/2/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/5

Ms. Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401



SUBJECT: Lonza Formulation LS-22
EPA Registration Number: 6836-181
Application Date: December 11, 2009
Receipt Date: December 15, 2009

Dear Ms. Joanna Holcombe:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below:

- Request to change name of record
- Update Storage and Disposal Language

1) As per your request the name of record has been changed for this product from Bio-Guard LS-22 to Lonza Formulation LS-22. As such delete the following text at the bottom of page 1: "(Primary Brand Name is Bio-Guard LS-22)".

2) Revise the Precautionary to be in agreement with the Label Review Manual by beginning the statement with the word Corrosive: "**DANGER Corrosive**. Causes irreversible eye damage..." In addition, add the following text: "...Wash thoroughly with soap and water after handling *and before eating, drinking, using tobacco or using the toilet*. Remove contaminated..."

3) Add the following to the Environmental Hazards statements such that this section will reflect the environmental concerns associated with this active ingredient: "*This pesticide is toxic to fish. Do not discharge...*"

CONCURRENCES

SYMBOL	7510P						
SURNAME	S. Jones						
DATE	2/11/10						

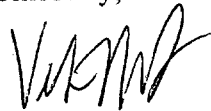
4) Add two reference asterisks to your label to clearly identify the organisms against which this product is effective. Add an asterisk to the fourth section on page 2 after the statement ending "...a wide variety of gram-positive and gram-negative bacteria.*" and add an asterisk to the beginning of the third section on page 3 beginning: "* This disinfectant is effective at 4 oz./gal (1:31) against..."

5) Revise the Directions for Use by correcting the For Disinfections directions on page 2 as follows: "...then be rinsed with *potable* water or wiped with a clean..." Since the label indicates that this product is not for use on food contact surfaces, clarify the use on appliances in this same section by indicating "*exterior surfaces of appliances.*"

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling. Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510P)

Enclosure: Stamped Label
 7510P:T.Lantz:2/27/10:6836-181 amendment

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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LONZA FORMULATION LS-22

LEMON ODOR-DISINFECTANT-DEODORANT

* Kills Pseudomonas, Salmonella and Staphylococcus

ACTIVE INGREDIENT:

Alkyl (C₁₄, 58%; C₁₆, 28%; C₁₂, 14%)
dimethyl benzyl ammonium chloride 2.50%

OTHER INGREDIENTS: 97.50%

TOTAL INGREDIENTS: 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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.

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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

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

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Registration No. 6836-181
EPA Establishment No. _____
Net Contents _____
[Country of origin (insert country)]
[Manufactured in (insert country)]
[Barcode]

ACCEPTED
with OP
in EPA Lab
MAR 12 2010

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **6836-181**

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

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**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Causes irreversible eye damage. Do not get in eyes, on skin, or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash contaminated clothing before reuse. Wear rubber gloves and goggles, face shield or safety glasses when handling. Harmful if swallowed.

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.

THIS DISINFECTANT reduces the surface tension of water, improving its wettability. Microbes are capable of mass reproduction in sub-visible pores, scratches and cracks of surfaces. The excellent wettability of THIS PRODUCT improves the penetration of the use solution into areas that otherwise might not be reached.

THIS DISINFECTANT is effective against a wide variety of gram-positive and gram-negative bacteria. It is also an excellent deodorant and is especially effective in controlling odors that are bacterial in origin. Has a pleasant lemon odor.

THIS DISINFECTANT mixes with water to form clear, stable use solutions. Use solutions are non-corrosive and non-staining to plastic, vinyl, synthetics, enamel, tile and most common metals.

DIRECTIONS FOR USE

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

(Note to reviewer: Only One of the following two statements will 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.

Apply the use solution with a clean mop, sponge, cloth, squeegee, mechanical scrubber or mechanical spraying device. Prepare fresh solutions daily. Do not reuse solutions. Discard solutions when they become visibly soiled.

For Disinfection - thoroughly wet surfaces to be treated. Surfaces must remain moist for at least 10 minutes to assure proper germicidal action. If desired, surfaces may then be rinsed with clean water or wiped with a clean, damp cloth to remove suspended soils. This product may be used for cleaning and deodorizing, one-step cleaning, and disinfection or as a disinfectant of pre-cleaned, hard, non-porous, inanimate environmental surfaces such as glass, metal, glazed porcelain, linoleum, tile, smooth leather, vinyl, enamel and finished wood surfaces. Apply this product to walls, floors, appliances and furnishings.

This product may be used through automatic floor scrubbing equipment.

This product must not be used on food contact surfaces.

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

MAR 12 2010

**Under the Federal Insecticide,
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registered under EPA Reg. No.**

6836-181

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CLEANING

To Clean and Deodorize or to Pre-clean Prior to Disinfection. Depending on the soil level of the area to be cleaned, use 8 to 16 oz. of THIS PRODUCT per gallon of water.

DISINFECTING

Hospitals, Veterinary Clinics, Nursing Homes: Use 1 part of THIS PRODUCT per 22 parts of water (5 1/2 oz./gal.) for one-step cleaning and disinfection of areas with light to medium soil loads. For heavily soiled areas, pre-clean as described above, then disinfect with THIS PRODUCT at 1 part to 31 parts water (4 oz./gal.).

* This disinfectant is effective at 4 oz./gal. (1:31) against Pseudomonas aeruginosa PRD-10, Salmonella enterica ATCC 10708, and Staphylococcus aureus ATCC 6538 when tested by the A.O.A.C. Use Dilution Test Method for pre-cleaned, hard nonporous, inanimate environmental surfaces.

Industrial areas, Barber Shops, Restrooms, Restaurants, Food and Meat Processing Plants (non-food processing areas), Other Non-Medical Uses: Pre-clean surfaces, then disinfect with a solution of 1 part of THIS PRODUCT in 50 parts of water (2 1/2 oz./gal.). Alternatively, clean and disinfect in one operation using 5 1/2 oz. of THIS PRODUCT per gal. of water.

For deodorizing garbage cans, garbage trucks, industrial waste receptacles and garbage handling equipment. It is especially important to pre-clean for the product to perform properly, then apply a wetting concentration of 12 oz. of THIS PRODUCT per gallon of water.

For Mildew Control: Follow directions for hospital disinfection. Repeat treatment every seven days, or when new growth appears.

(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses -- all sizes -- No Reuse/Rinsate Statement for Public Health Use products)

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 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. **(For metal containers only: DO NOT cut or weld metal containers.)** **(For 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.

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