UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



United States Environmental Protection Office of Pesticide Programs

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

2009 NOV

Subject:

Lonza Disinfectant M-15

Registration No.:

6836-166

Amendment Dated:

August 19, 2009

Submission #:

857026

Dear Ms. Holcombe,

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

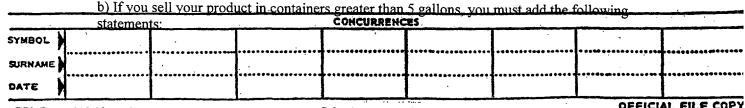
Proposed Amendment

- Add optional barcode, "country of origin" statement and "manufactured in" statement;
- Update the company address;
- Revise Salmonella choleraesuis to its new name Salmonella enterica;
- Update the Storage and Disposal language per PR Notice 2007-4

Conditions

Revise the label as follows:

- 1) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern. Delete the "Storage and Disposal" Instructions for containers one gallon or less w/ uses other than household/residential. Also revise the second "Note to reviewer" to read "Containers institutional/industrial/commercial uses."
- 2) The Container Rule established rinsate instructions for commercial, institutional, and industrial containers sold in containers five gallons or less and containers greater than five gallons. Therefore, revise the "Container Disposal" statements as follows:
 - a) Your proposed "Container Disposal" statements are acceptable for containers five gallons or less. You need to add the following descriptor above the statement, "(Containers 5 gallons or less)."



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

(Container greater than 5 gallons)

Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. 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. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

- Page 2) Remove the first aid statement from page two and place it on page one.
 - Under the "Environmental Hazard" section please include the statement, "This product is toxic to fish and other aquatic organisms".

General Comments:

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Velma Noble PM Team 31 at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely

Velma Noble,

Product Manager, Team 31

Regulatory Management Branch

Antimicrobials Division (7510P)

Enclosure:

Stamped Label

LONZA FORMULATION M-15

DISINFECTANT-CLEANER-DEODORANT

PLEASANTLY MINT SCENTED

ACCEPTED with COMMENTS in EPA Letter Dated

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, tegistered under EPA Reg. No. 6836-166

Active Ingredient: Alkyl (C₁₄, 58%; C₁₆, 28%; C₁₂, 14%) Other Ingredients: 96.0%

Contains methyl salicylate

KEEP OUT OF REACH OF CHILDREN

DANGER

See (left) (right) (side) (back) panel for Precautionary Statements and First Aid

EPA Reg. No.

6836-166

EPA Est. No.

(insert EPA Est. No. here)

Net Contents: (insert container size here)

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Manufactured by: LONZA INC 90 Boroline Road Allendale, NJ 07401

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PRECAUTIONARY STATEMENTS HAZARD 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 protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves. Harmful if swallowed or absorbed through the skin. Wash thoroughly with soap and water after handling. 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 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.

(for containers 5 gallons or greater)

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 is effective against a wide variety of gram-positive and gram-negative bacteria.

THIS DISINFECTANT is also an excellent deodorant. It is especially effective in controlling odors that are bacterial in origin.

THIS DISINFECTANT mixes readily with water and makes a clear, stable solution. In use dilution, it is non-corrosive and non-staining to plastic, vinyl, synthetics, enamel, tile and most common metals. Has a pleasant mint odor.

DIRECTIONS FOR USE

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

USE LONZA FORMULATION M-15 ON hard, non-porous inanimate surfaces such as glass, metal, plastic, glazed porcelain, linoleum, glazed tile, leather, vinyl, enamel and finished wood surfaces. Apply this product on walls, floors, appliances and furnishings in industrial and commercial offices, restrooms and work areas.

CLEANING AND DEODORIZING. Whenever practical, flush away gross soils with water. For cleaning and deodorizing, use 2 1/2 to 4 ounces of THIS PRODUCT per gallon of water. Cleaning may be accomplished with a clean mop, sponge, squeegee, wet vacuum system or a mechanical spraying device. After cleaning, remove suspended soils with a clear water rinse, vacuum pickup or by wiping with a clean mop, sponge, squeegee or cloth.

DISINFECTING. Before disinfecting, pre-clean surfaces as directed above. Then, prepare 2 1/2 oz. of THIS DISINFECTANT per gallon of water and thoroughly wet the hard nonporous surfaces with mop, sponge, squeegee, or mechanical spraying device. The disinfecting solution must contact the surface for 10 minutes for proper disinfection. If desired, the surfaces may then be rinsed with clear water or wiped with a damp cloth.

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 as a disinfectant.

Prepare a fresh solution daily or more often if it becomes diluted or spoiled. For sprayer applications, the coarse spray device. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist.

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FOR CLEANING AND DEODORIZING OF GARBAGE CANS, GARBAGE TRUCKS, INDUSTRIAL WASTE RECEPTACLES AND OTHER GARBAGE HANDLING EQUIPMENT. It is especially important to pre-clean in order for the disinfectant to perform properly. Then apply a wetting solution of 8 ounces of THIS PRODUCT per gallon of water.

FOR CLEANING OF WALLS, FLOORS AND INDUSTRIAL WORK AREAS. Use 2 - 4 ounces per gallon of water. The use of rubber gloves is recommended for personnel doing continuous hand cleaning.

KILLS: Salmonella enterica ATCC 10708, Staphylococcus aureus ATCC 6538, Streptococcus pyogenes ATCC 9342, Escherichia coli ATCC 11229, Enterobacter aerogenes ATCC 13048, Shigella sonnei and Candida albicans.

This DISINFECTANT may be used through automatic floor scrubbing equipment.

(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household and Residential)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children.

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate.

(Note to reviewer: For Nonrefillable Containers, Container is over one gallon)

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 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:) 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. DO NOT cut or weld metal containers.