

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

June 1, 2005

Robert J. Sloan
LONZA, Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Bio-Dine LF-II
EPA Registration No. 6836-195
Submission Date: March 25 2005
Receipt Date: March 28, 2005

Dear Mr. Sloan:

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

- Revised label per PR Notices (2001-1)
- Revisions per November 25, 2003, Agency letter

Condition

The first sentence under the Environmental Hazards statement should read as follows:

"This product is toxic to fish and other aquatic organisms."

General Comments

The aforementioned condition should be handled at the next printing of the label.

A stamped copy of the labeling accepted with the condition is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL	75/0C						
SURNAME	HENSON						
DATE	6-1-05						

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Wash thoroughly with soap and water after handling. Avoid contamination of food and foodstuffs. Remove contaminated clothing and wash 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(If container size is greater than gallon, the following storage and disposal 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.

BIO-DINE LF-II

**GERMICIDAL
DETERGENT
SANITIZER**

**A Low-Foaming Sanitizer For Food,
Meat and Beverage Industries.**

**For use in Federally Inspected
Meat and Poultry Plants.**

FOR INDUSTRIAL USE

Active Ingredient:	
Iodine *.....	3.5%
Other Ingredients.....	96.5%
Total Ingredients.....	100.0%

* from Polypropoxypolyethoxyethanol-iodine complex

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 6836-195

EPA Est. No. (insert EPA Establishment number here)

Net Contents: (insert container size here)

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

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

JUN - 1 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. **6836-195**

DIRECTIONS

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

USE SOLUTION PREPARATION

Determine the total number of gallons required for your application. Divide the number of gallons required by the following factor to determine the ounces of sanitizer to be added to achieve the proper ppm of iodine:

- For 50 ppm - divide by 6.5
- For 25 ppm - divide by 13
- For 12-1/2 ppm - divide by 26

Example: To prepare 104 gallons of a 25 ppm iodine solution. Divide 104 by 13: $104/13 = 8$ ounces of product should be added to 104 gallons of water for a 25 ppm solution.

Always prepare fresh sanitizing solutions and use them the same day prepared. All sanitizing solutions should contact surfaces at least two minutes prior to rinsing. When circulating sanitizing solutions through CIP systems, allow at least 5 minutes contact.

No potable water rinse is required for sanitizing solutions containing 25 ppm titratable or less if treated surfaces are thoroughly drained. Titratable iodine solutions above 25 ppm require rinsing.

FOOD AND BEVERAGE SANITIZATION PROCEDURES

SOFT DRINK PLANTS: Thoroughly rinse bottling and premix dispensers with water. Drain thoroughly and fill equipment with 25 ppm solution (refer to use solution chart). Just before resuming operation, flush the 25 ppm solution from equipment with potable water. When changing over between soft drink flavors, rinse system well with water, flush with 25 ppm solution and rinse with potable water.

SANITIZING BOTTLES AND CANS: Proportion into the final rinse of the container washer or rinses in concentration of 12.5 ppm titratable iodine.

SANITIZING STORAGE TANKS: After cleaning use a 25 ppm solution for sanitizing beer fermentation and holding tanks. Use solution can be applied by spraying or can be used in conjunction with automated clean-in-place systems. Do not rinse.

EQUIPMENT IN POULTRY, MEAT, RABBIT, EGG PROCESSING PLANTS, FROZEN AND FRESH PACK PROCESSING PLANTS: To clean equipment, scrub surfaces with a mop, brush, sponge or cloth using 50 ppm solution or use another suitable detergent for cleaning. Rinse with potable water. For sanitizing previously cleaned surfaces, apply 25 ppm solution by spraying, flushing, or with a clean sponge. Thoroughly wet surface and allow to thoroughly drain. Do not rinse.

MILK, CITRUS AND ICE CREAM PROCESSING PLANTS: Apply routinely as a sanitizing spray (12-1/2 ppm to 25 ppm titratable iodine) on walls, conveyors, equipment and floors to reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate bacteria associated with condensation on equipment and pipes. Regular use as a sanitizer at 25 ppm helps prevent milk stone formulation on equipment.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than gallon, the following storage and disposal statements will be used:)

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 or mixture of 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

(Plastic containers): Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities by burning. If burned, stay out of way of smoke.

(Metal Containers:) Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.