

74234-1

6/18/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Agency Information: Date of Issuance: JUN 18 2008; Number: 74234-1; Term of Issuance: Conditional; Name of Pesticide Product: LMP-102

NOTICE OF PESTICIDE:
[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Intralytix, Inc
323 W. Camden Street
Baltimore, MD 21201

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act.

This product (OPP Decision No. D-342291) is conditionally registered in accordance with FIFRA sec 3(c)(7)(C) provided that you:

- 1. A monitoring plan must be prepared and submitted that is designed to support the responsible use of this bacteriophage product. The monitoring plan will be submitted for EPA review and approval within two months after the registration date.

Monitoring Plan

A monitoring plan designed to observe and address bacteriophage resistance is required. The results of the monitoring are to be reported to the Agency. The components of each document are listed below:

Signature of Approving Official:

Handwritten signature of Velma Noble

Velma Noble

Date:

JUN 18 2008

Product Manager Team-31

CONCURRENCES

Table with columns for SYMBOL, SURNAME, DATE, and multiple empty rows for CONCURRENCES.

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The monitoring plan submitted on July 8, 2005 and reviewed by the Agency must be amended to include:

- (1) Recording of consistency of use conditions (temperature, humidity, and use patterns)
- (2) An explicit description of how the strains of "presumptive *Listeria monocytogenes*" are characterized at the production laboratory. It will be important to speciate them before concluding that there is resistance to *L. monocytogenes*. Some description of the speciation methods planned, and the Q/A involved, is required. Food processing facilities are not likely to want to have their strains speciated, or at least not likely to want the results generally available, so a discussion of how that information would be handled is warranted.
- (3) This criteria must be used in selecting new monophages for inclusion:
 - a. The new monophage is lytic for *Listeria monocytogenes* strain(s);
 - b. The new monophage satisfies the "lytic phage" criteria, as defined by (i) plaque morphology (clear plaques), and (ii) target range (lytic against ≥ 5 genetically-diverse— as defined by PFGE—*L. monocytogenes* strains).
 - c. The new monophage does not contain bacterial toxin-encoding genes listed in 40 CFR § 725.421.
 - d. The new monophage does not contain bacterial 16S ribosomal RNA gene sequences.

Each accepted "new monophage" will be characterized in the same rigorous manner as were all of the monophages currently contained in LMP-102. Specifically, for each monophage this will include:

- Phage morphology characterization, by naked eye inspection and/or light microscopy
- Taxonomy determination, by electron microscopy
- DNA size estimation and purity determination, by pulsed field gel electrophoresis (PFGE)
- Full genome sequencing and analysis for the presence of bacterial-toxin encoding genes listed in 40 CFR § 725.421, and bacterial 16S ribosomal RNA gene sequences
- Genetic fingerprinting, by restriction fragment length polymorphism (RFLP)
- Protein fingerprinting, by SDS-PAGE

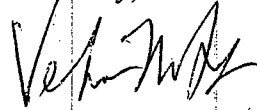
Monitoring Plan Report

A Monitoring plan report must be submitted to the Agency every 6 months or as data is acquired (whichever is shorter). It must include:

- (1) The "phage removal and replacement" strategy when resistance is observed;
- (2) A new CSF;
- (3) Chemistry data and any other relevant information including the conditions in which the resistant bacterium was identified must be submitted to support changes in the cocktail preparation;

SYMBOL									
SURNAME									
DATE									

Sincerely,



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

Enclosure: Stamped Label
Efficacy Data Evaluation

Precautionary Statements

Hazards to Humans and Domestic Animals
Avoid contact with eyes, skin or clothing.
Wash thoroughly with soap and water after handling.

Environmental Hazards

(If container size is 5 gallons or greater, the following statement will be included on the label).
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 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.

Product Description

LMP-102 is a novel, non-chemical approach for controlling the pathogen, *Listeria monocytogenes*. It is specifically designed for use in food-processing plants and food-handling establishments where *Listeria monocytogenes* is present. LMP-102 is ideal for use in HACCP programs that have identified *Listeria monocytogenes* as a hazard that is reasonably likely to occur. LMP-102 is a pH neutral formulation. It is compatible with all types of surfaces. LMP-102 does not corrode or damage environmental surfaces or equipment.

LMP-102™

Antimicrobial for Use

Against *Listeria monocytogenes*

For use in Food Processing Plants and Food-Handling Establishments

Laboratory testing has shown that LMP-102 kills 99% of *Listeria monocytogenes* within 5 minutes. The use of LMP-102 is a supplement to and not a substitute for standard sanitization practices; users must continue to follow all current microbial control practices including those related to cleaning and sanitization of environmental surfaces.

Active Ingredient

Listeria Monocytogenes Specific

Bacteriophages 0.00001%

Inert Ingredients..... 99.99999%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No. 74234-

EPA Est. No. To be assigned

Net Contents:

Intralytix, Inc.

323 W. Camden Street

Baltimore, MD

Directions for Use

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

LMP-102 is for use in the control of *Listeria monocytogenes* on non-food contact surfaces in food processing plants (poultry, meat, pork, etc.) and food-handling establishments. Surfaces that can be treated with LMP-102 include walls, floors, drains and grating and non-food contact equipment.

Use LMP-102 as part of an integrated microbial control program with EPA approved sanitizers. Apply LMP-102 at least 5 minutes prior to using the sanitizer product.

Apply LMP-102 to surfaces by spraying or with a cloth or sponge. Apply sufficient amounts of LMP-102 so that the target surface is thoroughly covered. About 50 ml of LMP-102 will treat approximately 4 1/2 ft² of surface. Allow LMP-102 to remain on the treated surface for a minimum of 5 minutes.

APPROVED
FOR CONTROL OF
Listeria monocytogenes
IN FDA Registered Establishments

JUN 18 2008

4/10/08

Under the Federal Food, Drug, and Cosmetic Act, this product is deemed to be a drug and is subject to FDA regulation.

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STORAGE AND DISPOSAL

Storage: Store in original plastic container at 4° C.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

Container Disposal: 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.