

6836-238

4/2/2012

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Ms. Leesha N. Square
Regulatory Specialist for,
Lonza, Inc.
90 Boroline Road
Allendale, NJ 07401

APR -2 2012

Subject: Isocil

EPA Registration Number 6836-238
Your Notification Dated March 8, 2012
EPA Received Date March 9, 2012

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to update the product labeling as per our letter of February 16, 2012, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

A handwritten signature in black ink that reads "M Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

2087

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 5-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 6836-238	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Isocil	PM # 33	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Label Notification to update label verbiage per EPA suggestion.
Please see additional page for certification of notification statement per PR Notice 98-10.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	If "Yes" Unit Packaging wgt. No. per container		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Leesha N. Square	Title Regulatory Specialist	Telephone No. (Include Area Code) (678) 627-2238
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Leesha N. Square</i>	3. Title Regulatory Specialist	
5. Typed Name Leesha N. Square	5. Date March 8, 2012	



Via Fed Ex

Mr. Marshall Swindell, PM-33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401
USA

Leesha N. Square
Lonza Microbial Control
Commercial Regulatory Services

Tel: 678-627-2238
Fax: 678-627-2081
Leesha.square@lonza.com

March 8, 2012

**SUBJECT: Isocil, EPA Reg. No. 6836-238
Application for Label Notification**

Dear Mr. Swindell:

I am submitting an application to update the product label per the suggested label revisions that were included in the CSF acceptance letter dated February 16, 2012. Revisions to the label have been made under the Precautionary Statements and Direction for Use sections.

We disagree with your suggestion in regards to placing a box around the Storage and Disposal section. It is not required by the provisions of PR notice 2007-4. Also, the label review manual states that "Blocking these statements with a solid line (a box) is *suggested* as a means of increasing their prominence." This does not mean that blocking with a box or line is required. All of our final printed labels do employ a bold heading for the storage & disposal section that sets it apart and increases its prominence, so the stipulation of the label review manual is therefore satisfied. We feel that our label has been properly formatted and a box is not necessary.

Please find the enclosed documents in support of this notification:

- Application for pesticide (8570-1)
- Certification of Notification Statement
- 1 copy of the CSF acceptance letter
- 1 copy of proposed label with changes highlighted
- 2 copies of proposed label

If you have any questions or need any additional information, please feel free to contact me at 678-627-2238.

Sincerely,
Lonza Inc.

Leesha N. Square
Regulatory Specialist



Via Fed Ex

Mr. Marshall Swindell, PM-33
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
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Leesha N. Square
Lonza Microbial Control
Commercial Regulatory Services

Tel: 678-627-2238
Fax: 678-627-2081
Leesha.square@lonza.com

March 8, 2012

Certification of Notification Statement

Per PR Notice 98-10

Isocil

EPA Reg. No. 6836-238

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sincerely,
Lonza, Inc.

Leesha N. Square
Regulatory Specialist

ISOCIL

FOR MANUFACTURING USE ONLY
INDUSTRIAL MICROBICIDE

Active Ingredients:

5-chloro-2-methyl-4-isothiazolin-3-one	10.80%
2-methyl-4-isothiazolin-3-one	3.83%
Inert Ingredients:	85.37%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER



POISON



(Danger, Poison and Skull/Crossbones will be printed in RED)

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.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. 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.

SEE SIDE PANEL FOR PRECAUTIONARY STATEMENTS.

EPA Reg. No. 6836-238

EPA Est. No. *(as indicated on container)*

Net Contents: *(as indicated on container)* ~~GENERAL: Consult Federal, State or local disposal authorities for approved alternative procedures.~~

MANUFACTURED FOR:

Lonza Inc., 90 Boroline Road

Allendale, NJ 07401

6836-IL-1

ISOCIL (6836-238)

EPA Stamped Label 11-24-04 with 3-3-10 Notification and 2-16-12 CSF Approval Conditions Page 1 of 3

5067

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

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Fatal if absorbed through skin. Do not get in eyes, on skin, or on clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Harmful if inhaled. **HARMFUL IF INHALED**
Wear goggles or face shield, protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse. ~~This product may cause skin sensitization reactions in some people. Wear goggles or face shield, protective clothing and rubber gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. Avoid breathing vapor, or spray mist.~~

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders and others exposed to methylisothiazolinone products must wear:

- protective eyewear
- chemical-resistant gloves
- long-sleeve shirt and long pants
- chemical-resistant apron
- socks and chemical resistant footwear

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly.

ENVIRONMENTAL HAZARDS

This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates. 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.

10047

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons.

Only for formulation into industrial Algaecides, fungicides, preservatives and/or bactericides.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE

The product as supplied evolves gas (largely carbon dioxide) slowly. To prevent buildup of pressure, the product is packaged in a specially vented container. Keep this product in the original container when not in use. Container must be stored and transported in an upright position to prevent spilling the contents through the vent.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide 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.

(METAL CONTAINERS): Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(PLASTIC CONTAINERS): Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. 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.

7087