

6836-208

12-28-2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

DEC 28 2011

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Subject: Glycoserve II Preservative
EPA Registration No.: 6836-208
Notification Date: 12/05/2011
EPA Receipt Date: 12/08/2011

Dear Ms. Holcombe,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

- Update of Container Disposal statements as per PR Notice 2007-4
- Optional Spanish signal word
- Placeholder for non-FIFRA DOT Symbols
- Optional Spanish statement and English translation

General Comments

Based on a review of the submitted materials, your notification for the items listed above is acceptable. It is in compliance with PR notice 91-2 and in agreement with the label.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline Campbell-McFarlane
Jacqueline Campbell-McFarlane
Product Manager (34)

Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	SURNAME	DATE					

EPA

United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

Application for Pesticide - Section 1

1. Company/Product Number 6836-208		2. EPA Product Manager Jacqueline McFarlane		3. Proposed Classification	
4. Company/Product (Name) Glycoserve II Preservative		PM# 34		<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:		
<input type="checkbox"/> Check if this is a new address			EPA Reg. No. Product Name		

Section - II

- Amendment - Explain below.
- Resubmission in response to Agency letter dated _____
- Notification - Explain below.
- Final printed labels in response to Agency letter dated _____
- "Me Too" Application
- Other - Explain below

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

Not Subject to PRIA

Label Notification to correct container disposal directions, etc. Please see cover letter for details.

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.

Signature: *Joanna Holcombe* Date: *12-5-11*

Section - III

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

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9297
2. Signature <i>Joanna Holcombe</i>		6. Date Application Received (Stamped)
3. Title Sr. Commercial Regulatory Services Associate		
4. Typed Name Joanna Holcombe		
5. Date <i>12-5-11</i>		

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.

Via FedEx

Ms. Jacqueline McFarlane, PM-34
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2227 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201-696-3470
joanna.holcombe@lonza.com

December 5, 2011

**SUBJECT: Glycoserve II Preservative, EPA Reg. No. 6836-208
Application for Label Notification**

Dear Ms. McFarlane:

I am submitting an application to correct the Container Disposal directions for the abovementioned product label. This product is not a dilutable formulation, therefore, the "Triple rinse (or equivalent)" language should not have been changed when the other Storage and Disposal changes were made per PR Notice 2007-4. That language has been restored, and the note to reviewer altered.

Additional changes to the label include:

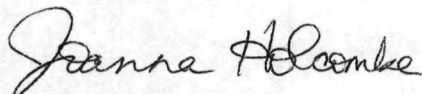
- Optional Spanish signal word;
- Placeholder for non-FIFRA DOT Symbols; and
- Optional Spanish statement and English translation:
*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

Please find the enclosed documents in support of this notification:

- Application for Notification;
- Certification with Respect to Label Integrity;
- CD with label; and
- One copy of the proposed label with changes highlighted.

If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,
Lonza Inc.



Joanna Holcombe
Sr. Commercial Regulatory Services Associate

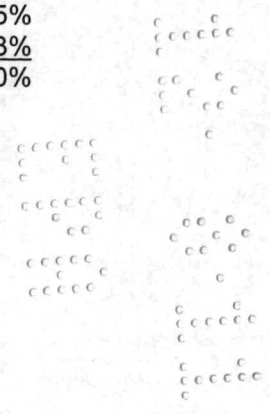
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GLYCOSERVE II PRESERVATIVE

FOR MANUFACTURING USE ONLY

Active Ingredients:

1,3-Bis (hydroxymethyl)-5,5-dimethylhydantoin	33.2%
1-(hydroxymethyl)-5,5-dimethylhydantoin	31.5%
Other Ingredients	35.3%
Total	100.0%



KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

EPA Registration No. 6836-208
 EPA Establishment No. 6836-PA-01
 Net Weight (As marked on container)

[DOT Symbols]
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

Emergency Contact Number: (_____)

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

NOTIFICATION
 Date Reviewed: 12/28/2011
 Reviewed By: J. Cal

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, inhaled or absorbed through the skin. Causes Moderate eye irritation Avoid contact with skin, eyes or clothing. Wear chemical resistant gloves when using this product. Wash thoroughly with soap and water after handling. 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 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.

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.

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.

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*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

DIRECTIONS FOR USE

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

Use GLYCOSERVE II PRESERVATIVE to manufacture products that are used to control bacteria and fungi in liquid detergents, soft soaps, water-based paints for household and Industrial use, room deodorizers and air fresheners, water-based surfactants, polymer emulsions, protective or decorative coatings, water-based gels for household and Industrial products, textiles, water-based inks, and non-food contact water-based adhesives and latex for paper coatings.

Formulators and repackagers of this product must obtain their registrations from the Environmental Protection Agency.

{Note to reviewer: For Nonrefillable Containers, not a dilutable product. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Refrain silent on burning;" therefore, no incineration language is provided for plastic containers.}

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 (or equivalent). Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill.

{Metal containers only:} DO NOT cut or weld metal containers.

{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.