

6836-208

12-08-2009

1/8



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

DEC 8 2009

OFFICE OF
PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

FILE COPY

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Notification per PR Notice 98-10
Glycoserve II Preservative
EPA Registration No. 6836-208
Application Date: November 17, 2009
Receipt Date: November 18, 2009

Dear Ms. Holcombe:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification:

- Update Storage and Disposal language per PR Notice 2007-4
- Add optional barcode, "country of origin" statement, and "manufactured in" statement
- Update company address

General Comment:

Based on a review of the material submitted, the following comment applies:

The notification is acceptable.

Should you have any questions concerning this letter, please contact Heather Garvie at (703) 308-0034 or by email address at garvie.heather@epa.gov.

Sincerely,

ShaRon Carlisle
(Acting) Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
--	--	-----------------------

Application for Pesticide - Section I

1. Company/Product Number 6836-208	2. EPA Product Manager ShaRon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Glycoserve II Preservative	PM# 34	
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.)

Not Subject to PRIA

Label Notification to update Storage and Disposal language per PR Notice 2007-4.

PLEASE READ 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: *11/17/09*

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 <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package 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)	
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 labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____	
				<input type="checkbox"/> Paper glued	
				<input 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
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 both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Joanna Holcombe</i>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date November 17, 2009	

34

3
6



Via FedEx

Ms. ShaRon Carlisle, Acting PM-34
Document Processing Desk (NOTIFY)
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

Joanna Holcombe
November 17, 2009

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

Dear Ms. Carlisle:

I am submitting an application to accomplish the following for the above named product:

- Add optional barcode, "country of origin" statement, and "manufactured in" statement;
- Update the company address;
- Update the Storage and Disposal language per PR Notice 2007-4.

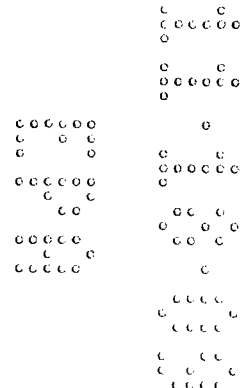
Please find the enclosed documents in support of this notification:

- Application for Notification;
- One copy of the proposed label with changes highlighted; and
- Two copies of the proposed label

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



GLYCOSERVE II PRESERVATIVE

FOR MANUFACTURING USE ONLY

Active Ingredients:

1,3-Bis (hydroxymethyl)-5,5-dimethylhydantoin	33.2%
Hydroxymethyl-5,5-dimethylhydantoin	31.5%
Other Ingredients	<u>35.3%</u>
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Registration No. 6836-208
 EPA Establishment No. 6836-PA-01
 Net Weight (As marked on container)
 [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: 12/8/09
 Reviewed By: A. Harris

**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.

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 for commercial, industrial, and institutional uses)

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.

(Note to reviewer: This Container Statement will be used only for containers 5 gallons or less:)

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic and Metal Containers:) Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill.

(For metal containers only: DO NOT cut or weld metal containers.)

(For 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.

(Note to reviewer: This Container Statement will be used for containers over 5 gallons:)

Container Disposal:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic and 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. If not available, puncture and dispose in sanitary landfill.

(For 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.