

6836-307

01-11-2012

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JAN 11 2012

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

Subject: Dantoserve MS
EPA Registration No.: 6836-307
Application Date: December 12, 2011
EPA Receipt Date: December 13, 2011

Dear Ms. Holcombe,

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

Proposed Notification

LONZA, Inc is submitting additional label changes for the following:

- Modifying container disposal language for non dilutable formulation
- Add Spanish signal word
- Placeholders for non-FIFRA DOT symbols, Country or origin, country of manufacture, and barcode
- Update Lonza address
- Optional Spanish statement and English translation text

General Comments

Based on a review of the submitted materials, your notification for additional label changes as referenced above is acceptable. A copy of the accepted notification has been inserted in your file for EPA Reg. No. 6836-307.

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 Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@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
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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Environmental Protection Agency Washington, DC 20460	U.S. States <input type="checkbox"/> Registration... <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 6836-307	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dantoserve MS	PM# 34	
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: EPA Reg. No. Product Name	
<input type="checkbox"/> Check if this is a new address		

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 correct storage and 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: 12-12-11

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
*Certification must be submitted				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<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
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>Joanna Holcombe</i>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date <u>12-12-11</u>	

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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 12, 2011

**SUBJECT: Dantoserve MS, EPA Reg. No. 6836-307
Application for Label Notification**

Dear Ms. McFarlane:

I am submitting an application to restore the storage and disposal directions approved on March 11, 2010 via notification 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 (the September 30, 2010 stamped label). Also, the pesticide disposal language was changed in error. The correct language has been restored.

Additional changes to the label include:

- Optional Spanish signal word;
- Placeholders for non-FIFRA DOT Symbols, Country or origin, country of manufacture, and barcode;
- Update Lonza address;
- Note to reviewer stating language in [] is considered optional or interchangeable; 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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DANTOSERVE™ MS

MICROBIOCIDES

INDUSTRIAL PRESERVATIVE

Active Ingredients:

1,3-bis(hydroxymethyl)-5,5 dimethylhydantoin..	29.4%
1-(hydroxymethyl)-5,5-dimethylhydantoin	27.9%
1,2-benzisothiazolinon-3-one	1.1%
Other Ingredients:	41.6%
Total	100.0%



KEEP OUT OF REACH OF CHILDREN

CAUTION [PRECAUCIÓN]

See [side] [back] [left] [right] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-307
 EPA Est. No. 6836-PA-01
 NET CONTENTS: (As marked on container)

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

LONZA INC.
 90 Boroline Road
 Allendale, NJ 07401

NOTIFICATION
 Date Reviewed: 1/11/2012
 Reviewed By: AKM

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

CAUTION. Harmful if swallowed or inhaled. Avoid breathing vapor or spray mist. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

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

- long-sleeve shirt and long pants
- chemical-resistant gloves
- 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 REQUIREMENTS

Users must:

- 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.

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. Call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a 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.

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.

{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.

DANTOSERVE™ MS preserves and controls the growth of bacteria and fungi in aqueous dispersions of inorganic mineral slurries such as clay, kaolin clay, calcium carbonate and titanium dioxide used in the manufacture of food contact and non-food contact paper and paperboard for both filler and paper coatings applications.

The components of DANTOSERVE™ MS are acceptable under 21 CFR §176.170 and §176.180 for production of paper to be used for both dry, aqueous and fatty food contact.

DANTOSERVE™ MS should be added to the mineral slurry to be preserved at a rate of 0.05% to 0.30% [500 to 3,000 ppm] based on the total weight of the product to be protected.

To ensure uniform distribution, slowly disperse DANTOSERVE™ MS into the product with agitation. Mix thoroughly until evenly dispersed throughout the product.

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STORAGE AND DISPOSAL

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

Pesticide Storage: Keep container closed. Store in dry place. Do not store at elevated temperatures. Keep from freezing. Keep this product in the original container when not in use.

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

Nonrefillable container. Do not reuse or refill this container.

(Metal containers) Triple rinse or equivalent. 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 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.