

6836-119

9/16/2010

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

SEP 16 2010

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Dantogard
EPA Registration No. 6836-119
Notification Date: 08/26/2010
EPA Receipt Date: 08/30/2010

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 and PR Notice 2007-4

Proposed Notification


Restore the Pesticide Disposal Statement
PR 2007-4 Refillable Container Language

General Comments

Based on a review of the submitted materials, your Notification to Restore Pesticide Disposal Statement and add Refillable Container Language is acceptable and apart of the records on file.

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 Glen McLeod by telephone at (703) 347-0181 or by e-mail at mcleod.glen@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
Regulatory Management Branch
Antimicrobials Division (7510P)

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EPA Environmental Protection Agency Washington, DC 20460	United 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 1

1. Company/Product Number 6836-119	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dantogard	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

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 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: 8-26-10

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 *Certification must be submitted	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 or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>Joanna Holcombe</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date August 26, 2010	



Via FedEx

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

Ms. Jacqueline McFarlane, 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

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

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

August 26, 2010

**SUBJECT: Dantogard, EPA Reg. No. 6836-119
Application for Label Notification**

Dear Ms. McFarlane:

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

- Restore the Pesticide Disposal statement from the 5-19-04 EPA stamped label. This statement was changed in error;
- Remove "(For metal containers only: DO NOT cut or weld metal containers.)," which was previously added in error; and
- Add Refillable Container language per PR Notice 2007-4.

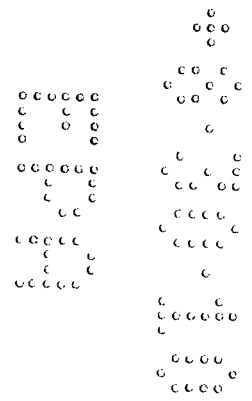
Please find the enclosed documents in support of this notification:

- Application for Notification;
- A copy of the 5-19-04 EPA Stamped label for EPA Reg. No. 6836-119;
- 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,

Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.



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DANTOGARD® PRESERVATIVE

PRESERVING YOUR CONFIDENCE
IN THE NEW MILLENNIUM

Contents: LIQUID

Active Ingredients:	
1,3-Bis (hydroxymethyl)-5,5-dimethylhydantoin ..	32.0%
Hydroxymethyl-5,5-dimethylhydantoin	7.5%
Inert Ingredients	60.5%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WEIGHT (as marked on container)
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

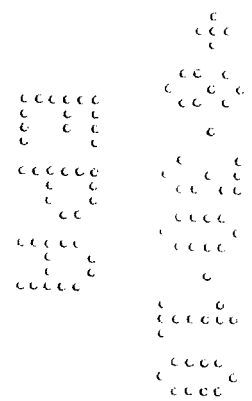
EPA Reg. No. 6836-119

EPA Est. # 6836-PA-1

Lonza Inc.
 90 Boroline Road
 Allendale, NJ 07401

Emergency Contact Number: (_____)

NOTIFICATION
 Date Reviewed: 9/13/10
 Reviewed By: G. M. pod



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

CAUTION: Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. 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. Call a poison control center or doctor for further treatment advice.

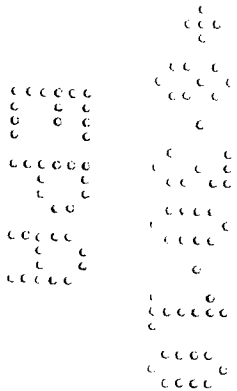
IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

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.

DANTOGARD preserves and aids in the control of the growth of bacteria and fungi in water based coatings (architectural coatings and water based emulsions), water based stains, sealants, adhesives, caulks, joint cements, resin emulsions, inks, textile processing chemicals (lubricants, sizing and coating compounds), liquid detergents, fabric softeners, soft soaps, household cleaners, 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 adhesives, sealants and caulks, latex for paper coatings, water based inks and water-based paints for industrial and household use.

DANTOGARD must be added to the formulation to be preserved at the rate of 3.4 to 13.8 lbs. per 1000 lbs. or 3,400 to 13,800 ppm based upon the total weight of the formulation to be protected.

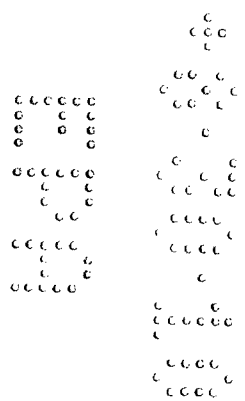
If the above articles have been treated with DANTOGARD, do not use them as components in materials used in food packaging and food-holding.

DANTOGARD preserves and controls the growth of bacteria in aqueous dispersions of inorganic minerals (clay-slurries) used in the manufacture of food-contact and non-food contact paper and paperboard. Use DANTOGARD at levels of 1.0 to 6.0 lbs. per ton of aqueous mineral slurry (500 - 3000 ppm).

ALTERNATE TEXT FOR ABOVE PARAGRAPH:

DANTOGARD 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.]

DANTOGARD may be used in metalworking fluids to prevent fungal growth at concentrations of 0.08% - 0.50%. Levels of DANTOGARD must be checked periodically since many cutting oils are unstable upon standing. Workers must take precautions to minimize inhalation exposure to metalworking fluid mists. OSHA limits for oil mist: Time Weighted Average (TWA = 5 mg/m³); Short Term Exposure Limit (STEL = 10 mg/m³).



(Note to reviewer: For Nonrefillable Containers for commercial, industrial, institutional uses. 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 "Remain 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:

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

(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 1/4 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 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 1/4 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.

(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: For Refillable Containers. 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 "Remain 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. Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose.

Pesticide Storage:

Open dumping is prohibited. Store in original container in areas inaccessible to children.

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:

Cleaning the container before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

(Plastic or Metal Containers:) To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

