

6836-119

8/22/2012

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AUG 22 2012

Patti Phillips
Sr Regulatory Services Associate
LONZA Inc
90 Boroline Road
Allendale, NJ 07401

Subject Dantogard™ Preservative
EPA Registration No 6836-119
Notification Date July 23, 2012
EPA Receipt Date July 24, 2012

Dear Ms Phillips,

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

Proposed Notification

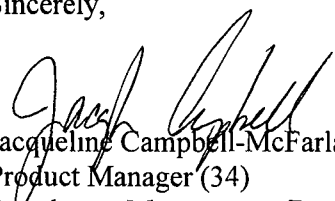
- Adding Not for Use in California to the master label

General Comments

Based on a review of the submitted materials, your notification to add Not for Use in California to the master label is acceptable. A copy of this letter has been made a part of the record on file for future reference

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)

CONCURRENCES										
SYMBOL	7510 P									
SURNAME	J. F. P.									
DATE	8/22/12									

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EPA 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 6836-119	2 EPA Product Manager Jacqueline McFarlane	3 Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4 Company/Product (Name) Dantogard 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 add Not For Use in California 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 Patti Phillips Date 7/23/12

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 <i>*Certification must be submitted</i>	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 <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)	If Yes Unit Packaging wgt	No per container
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 Patti Phillips		Title Sr Regulatory Services Associate		Telephone No. (Include Area Code) 201-316 9200	
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.					
2 Signature <u>Patti Phillips</u>				3 Title Sr Regulatory Services Associate	
4 Typed Name Patti Phillips		5 Date			
6 Date Application Received (Stamped)					

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

Patti Phillips
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201 316 9293
Fax 201 696 3463
patti.phillips@lonza.com

July 23 2012

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

Dear Ms McFarlane

I am submitting an application to add {Not for Use in California} to the Metalworking Fluid Preservation directions on page 3

Please find the enclosed documents in support of this notification

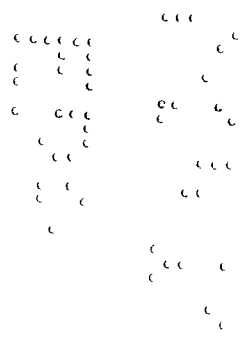
- Application for Notification
- One copy of the proposed label with changes highlighted and
- Two copies of the proposed label

If you have any questions or need any additional information please feel free to contact me at 201-316-9293

Sincerely
Lonza Inc



Patti Phillips
Sr Commercial Regulatory Services Associate



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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 [PRECAUCIÓN]

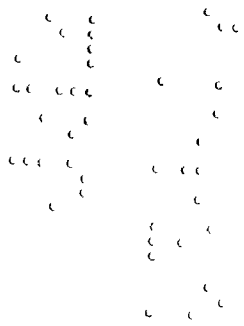
EPA Reg No 6836 119
EPA Est # 6836 PA 1
NET WEIGHT (as marked on container)

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

Lonza Inc
90 Boroline Road
Allendale NJ 07401

Emergency Contact Number (_____)

NOTIFICATION
Data Reviewed 2/22/12
Reviewed By [Signature]



**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

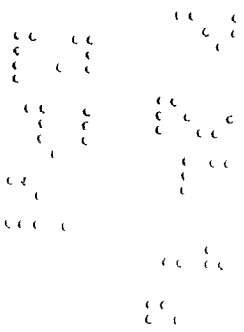
IF SWALLOWED Call a Poison Control Center or doctor immediately for treatment advice Have a person sip a glass of water if able to swallow Do not induce vomiting unless told to by a poison control center or doctor Do not give anything by mouth to an unconscious person

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



*{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

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 3400 to 13800 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

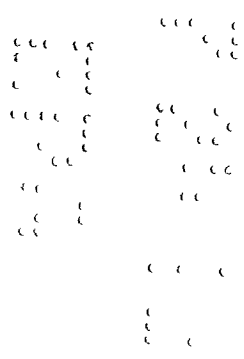
DANTOGARD preserves and controls the growth of bacteria in aqueous dispersions of inorganic minerals (clay slurries) used in the manufacture of food contact and non food contact paper and paperboard Use DANTOGARD at levels of 1.0 to 6.0 lbs per ton of aqueous mineral slurry (500 - 3000 ppm)

[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)

{Not for use in California}



{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 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

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

{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 Plastic or Metal Refillable 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 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 To clean the container before final disposal empty the remaining contents from this container into application equipment or mix tank Triple rinse (or equivalent)

