

6836-322

4/17/2014

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

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

APR 17 2014

Patti Golick, Sr. Regulatory Services Associate
Lonza, Inc.
90 Boroline Road
Allendale, N. J. 07401

Subject: Dantogard™ 2000 Preservative
EPA Registration No.: 6836-322
Notification Date: April 03, 2014
EPA Receipt Date: April 04, 2014

Dear Ms. Golick,

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

Proposed Notification

- Updating the label per PR Notice 98-10, to satisfy California data requirements.

General Comments

Based on a review of the submitted materials, updating the label to satisfy California data requirements per PR Notice 98-10 is **acceptable** and apart 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 hardy.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,

A handwritten signature in cursive script, appearing to read "Jacqueline Hardy".

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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EPA Environmental Protection Agency Washington, DC 20460	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 6836-322	2. EPA Product Manager Jacqueline Hardy	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dantogard 2000 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

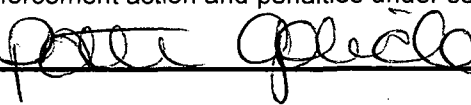
<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application
<input checked="" type="checkbox"/> Notification - 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. Please see cover letter for details.

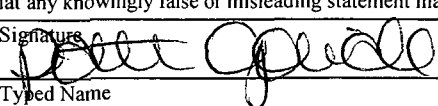
This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false 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:  Date: 4-3-14

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 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		<input 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 type="checkbox"/> Container		4. Size(s) Retail Container various		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 checked="" 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 Patti Golick	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) 201-313-9293
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 (Stampcd)
2. Signature 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Patti Golick	5. Date 4/3/14	

Via FEDEX

Ms. Jacqueline Hardy, PM-34
Document Processing Desk (NOTIFY)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Product
None
Active
(b) (4)
(b) (5)
Dewey

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

Patti Golick
Specialty Ingredients
Regulatory Assurance

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

April 3, 2014

**SUBJECT: Dantogard 2000 Preservative, EPA Reg. No. 6836-322
Application for Label Notification**

Dear Ms. Hardy:

I am submitting an application for notification for the above mentioned product label. The purpose of this amendment is to make the following changes based on efficacy data that was specifically conducted to satisfy California data requirements:

Page: 4

- Oil Field and Petrochemical Operations: reword the second paragraph, third sentence by adding "use levels" to the statement.
- Removed the Not for Use in California qualifier statement from Oil Field and Petrochemical Operations
- Water Foods/Initial Treatment: changed the use rates from 2,000 ppm to 120 ppm and 1.7 gallons to 0.10 gallons.

Page 5:

- Subsequent Treatment: changed the use rates from 2,000 ppm to 120 ppm and 1.7 gallons to 0.10 gallons.
- Continuous Treatment: changed the use rate from 0.6 gallons to 0.10 gallons.
- Drilling Muds, Packer Fluid, Fracturing Fluids, Completion and Workover Fluids: changed the use rates from 1,000 ppm to 100 ppm and 3.5 gallons to 0.35 gallons.
- Well Bore Clean Products, Hydraulic Fluids, Drilling Fluid Additives: changed the use rates from 3.5 gallons to 0.35 gallons.
- Hydrotesting: changed the use rates from 500 ppm to 120 ppm and 0.4 gallons to 0.10 gallons.

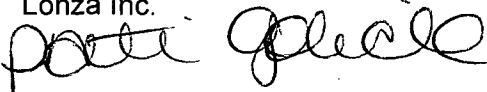
- Gas Storage Wells and Systems: changed the use rates from 2,000 ppm to 120 ppm and 1,500 ppm to 120 ppm.
- Slug Dose: changed the use rates from 2,000 ppm to 120 ppm and 1.7 gallons to 0.10 gallons, and also added "a designated time period" to the statement.
- Subsequent Treatment: changed the use rates from 1,500 ppm to 120 ppm and 1.3 gallons to 0.10 gallons.
- Continuous Treatment: changed the use rates from 750 ppm to 120 ppm and 0.6 gallons to 0.10 gallons.
- Pipeline Pigging: changed the use rates from 3,000 ppm to 120 ppm and 0.3 gallons to the range 0.05 to 4.8 quarts.

Please find the enclosed documents in support of this notification:

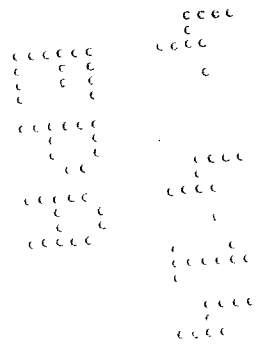
- Application for Notification;
- Certification with Respect to Label Integrity;
- CD with label;
- One copy of the proposed label with changes highlighted

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

Sincerely,
Lonza Inc.



Patti Golick



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

CAUTION: Causes moderate eye irritation. Harmful if swallowed, inhaled, or absorbed through the skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. Wear safety goggles or faceshield and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. 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 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.

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.

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

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.

(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 persons unfamiliar with its use.

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. Offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. 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.

(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. Offer for recycling, if available. 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.

(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.

DIRECTIONS FOR USE

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

DANTOGARD 2000 PRESERVATIVE preserves and aids in the control of the growth of bacteria and fungi in liquid detergents, soft soaps, water-based paints for household and Industrial use, room deodorizers and air purifiers, fresheners, water-based surfactants, polymer emulsions, protective or decorative coatings, water-based adhesives for household and Industrial products, textiles, water-based inks, and non-food contact water-based adhesives and latex for paper coatings and oil field applications including well bore cleaning products, drilling fluid additives, drilling muds, hydraulic fluids, workover, completion, fracturing and packer fluids, hydrotesting, water flooding, storage wells and systems, oil and gas production and transmission pipelines and systems and pipeline pigging and scraping operations.

Industrial and Household Applications

Add DANTOGARD 2000 PRESERVATIVE to the formulation to be preserved at the rate of 2.3 to 9.4 lbs. per 1000 lbs. or 2300 to 9400 ppm based upon the total weight of the formulation to be protected.

If the above articles have been treated with DANTOGARD 2000 PRESERVATIVE, do not use them as components in materials used in food packaging and food-holding.

DANTOGARD 2000 PRESERVATIVE may be used in metalworking fluids to prevent microbial growth at concentrations of 0.05 - 0.31% in the diluted metalworking fluid. Levels of DANTOGARD 2000 PRESERVATIVE 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). Formulators: Add DANTOGARD 2000 PRESERVATIVE to the metalworking fluid concentrate to achieve 0.05 - 0.31% in the diluted metalworking fluid. **{Not for Use in California}**

Oil Field and Petrochemical Operations

For oil field and petrochemical operations, use in closed delivery systems only.

Dantogard 2000 preserves and aids in the control of sulfate reducing bacteria and general aerobic bacteria, including microorganisms, in oil field recovery, processing, distribution and support systems such as water injection, produced lines, storage tanks and pipelines. Dantogard 2000 is effective for use in controlling microbial growth in fluids used in drilling, completion, workover and stimulation of oil wells. Specific treatment requirements vary among oilfield sites and subsystem components. Oil field fluids and subsystems most commonly requiring microbial contamination control are raw water sources, separators, ballast, storage, and mixing tanks, screens, surface injection equipment, production equipment (including injection and production piping casting, completion, and valving) and the formation itself. The primary point of treatment will vary among oilfield operations depending on the site problems, water-flood treatment methods and equipment.

Production addition must be made with a metering pump or similar device. This product must be slug fed, continuously fed, or fed on an intermittent basis depending on the degree of system fouling. The frequency, use levels, and duration of doses will vary with the individual systems and must be established through experience.

Water Floods {Not for Use in California}

Dantogard 2000 must be added to a water flood system at a point where uniform mixing will occur.

Initial Treatment:

When the system is noticeably contaminated, add 120 to 7,000 ppm Dantogard 2000 (0.10 to 5.9 gallons Dantogard 2000 per 1,000 gallons flood water) When added to a flowing system, slug dose for 4-6 hours based on flow rates. Repeat as necessary until control is achieved.

Subsequent Treatment:

Once control has been achieved, add 120 – 7,000 ppm Dantogard 2000 (0.10 to 5.9 gallons Dantogard 2000 per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Continuous treatment:

Dantogard 2000 can be dosed continuously at a level of 120 – 2,000 ppm (0.10 to 1.7 gallons Dantogard 2000 per 1,000 gallons flood water).

Drilling Muds, Packer Fluids, Fracturing Fluids, Completion and Workover Fluids

Dantogard 2000 must be added to these fluids at a point where uniform mixing will occur. Add 100 – 7,000 ppm Dantogard 2000 (0.35 to 24.7 gallons Dantogard 2000 per 100 barrels of fluid) to a freshly prepared fluid depending on severity of contamination.

Well Bore Cleaning Products, Hydraulic Fluids, Drilling Fluid Additives

Add 100 - 5,000 ppm Dantogard 2000 (0.35 to 17.7 gallons Dantogard 2000 per 100 barrels of fluid) to the formulation to be preserved.

Hydrotesting {Not for Use in California}

Water used to hydrotest pipelines or vessels must contain 120 – 7,000 ppm Dantogard 2000 (0.10 to 5.9 gallons Dantogard 2000 per 1,000 gallons flood water) depending on water quality and length of time equipment will be idle.

Gas Storage Wells and Systems {Not for Use in California}

Individual injection wells must be treated with 120 – 7,000 ppm Dantogard. Injections must be repeated as needed to maintain control.
Individual drips must be treated with a sufficient quantity of Dantogard 2000 to produce a concentration of 120 to 5,000 ppm Dantogard 2000 when diluted by the water present in the drip. Injections must be repeated as needed to maintain control.

Oil and Gas Production and Transmission Pipelines and Systems

Dantogard 2000 must be added at a point in the system where uniform mixing will occur. The application must be conducted to ensure maximum distribution of Dantogard 2000 through the entire internal surface of the pipeline. Injections to the system must be weekly, or as needed to maintain control.

Slug dose:

For a noticeably fouled system, add 120- 10,000 ppm Dantogard 2000 (0.10 to 8.4 gallons Dantogard 2000 per 1,000 gallons flood water) for a designated time period based on flow rates. Repeat as necessary until control is achieved.

Subsequent Treatment:

Once control has been achieved, add 120 – 5,000 ppm Dantogard 2000 (0.10 to 4.2 gallons Dantogard 2000 per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Continuous treatment:

Dantogard 2000 can be dosed continuously at a level of 120 – 2,500 ppm (0.10 to 2.1 gallons Dantogard 2000 per 1,000 gallons flood water).

Pipeline Pigging and Scraping Operations

Add Dantogard 2000 to a slug of water following the scraper. Add Dantogard 2000 at 120 - 14,000 ppm (0.05 to 4.8 quarts Dantogard 2000 per 100 gallons water) depending on the length of the pipeline and severity of biofouling.