



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

NOV 0 6 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

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

Subject:

Product Name: Dantogard 2000 Preservative

EPA File Symbol: 6836-322

Notification Application Date: June 28, 2012 Notification Pin Punch: October 18, 2012

Dear Ms. Phillips:

This acknowledges receipt of your Notification submitted in accordance with the provisions of PR Notice 98-10 under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification

Add the caveat "(Not for Use in California)" to the Metalworking Fluid preservation use and the Oilfield and Petrochemical Operations directions.

General Comments

Based on a review of the material submitted, the notification is acceptable.

Should you have any questions or comments concerning this letter, please contact Tom Luminello at (703) 308-8075.

Sincerely.

Jacqueline Campbell

Product Manager 34

Regulatory Management Branch II Antimicrobials Division (7510-P)

Please read instructions on reverse before con	npleting form. Form Ar	proved, OMB N	o. 2070-0060, Approval	expires 05-31-98	. •
	Ul States		☐ Registrat		OPP Identifier Number
EPA Environm	gency	Amendm		or radiation radiation	
	Vashington, DC 20460		☐ Athendin	Oilt	
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	Applic		sticide - Section 1		
Company/Product Number 6836-322			2. EPA Product Manager Jacqueline McFarlane		Proposed Classification
4. Company/Product (Name)		PM#		None Restricted	
Dantogard 2000 Preservative		34			None Restricted
5. Name and Address of Applicant (Include ZIP Code)			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:		
Lonza Inc. 90 Boroline Road	or identical	in composition and labe	ling to:		
Allendale, NJ 07401		EPA Re	g. No.		
		Product Name			
Check if this is a new address					
		Sectio	n – II		
Amendment - Explain below.		7			
Amendment - Explain below. Resubmission in response to Agency letter dated "Me Too" Application					
Notification - Explain below. 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 previous of DD Notice OC 40 and EDA regulations at 40 CED 450 40, and as all					
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					· · · · · · · · · · · · · · · · · · ·
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Signature:	y Company	<u> </u>	Date:	0011	<u> </u>
· ·		Section	n – III		
Material This Product Will Be Package This Product Will Be Package			W. Glill B.		
Child-Resistant Packaging Yes*	Unit Packaging Yes		Water Soluble Packag	ging	2. Type of Container Metal
No No	⊠ No				 .
*Certification must be	If "Yes"	No. per	If "Yes"	No. per	Plastic
submitted	Unit Packaging wgt.	container	Package wgt.	container	Glass
<i>Suommeu</i>		1			Paper
3. Location of Net Contents Information	4. Size(s) Ret	ail Container		5 Location of	Other (Specify) Label Directions
Label Container			•	On Label	·
	1 oz. to bu	lk		=	g accompanying product
6. Manner in Which Label is Affixed to Pr	roduct \(\sum \text{Lit}	nograph	Other		
		er glued			
	∑ Ste	nciled			
		Section			
1. Contact Point (Complete items directly			contacted, if necessary,	to process this appl	ication)
Name	Т	itle	1		Telephone No. (Include Area Code)
Patti Phillips		Sr. Regula	tory Services Ass	sociate	201-316 ES2S º
	Certificat	ion	<u> </u>		6. Daté Application Received
I certify that the statements I have made or			rue, accurate and comple	te. I acknowledge	C. C
that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. (Stamped					(Stamped)
2. Signature Action 3. Title Sr. Regulatory Services Associate					
4. Typed Name		Sr. Regula Date	tory Services Ass	sociate	- c c c t
Patti Phillips		6/28/12			ι το το του του του του του του του του τ

Lonza

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
Regulatory Services

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

June 28, 2012

SUBJECT: Dantogard 2000 Preservative, EPA Reg. No. 6836-322

Application for Label Notification

Dear Ms. McFarlane:

I am submitting an application to add {Not for Use in California} to the Metalworking Fluid directions on page 4 as well as the Oil Field and Petrochemical Operations Instructions.

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. Regulatory Services Associate

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DANTOGARD[™] 2000 PRESERVATIVE

PRESERVING YOUR CONFIDENCE IN THE NEW MILLENNIUM

Contents: LIQUID

Active Ingredients:

1,3-Bis (hydroxymethyl)-5,5-dimethylhydantoin

Hydroxymethyl-5,5-dimethylhydantoin

Other Ingredients

Total

33.2%

100.0%

KEEP OUT OF REACH OF CHILDREN CAUTION

Lonza Inc. 90 Boroline Road Allendale, NJ 07401

Emergency Contact Number: (_____

NET WEIGHT (as marked on container)

EPA Reg. No. 6836-322

EPA Est. # 6836-PA-1

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

Dantogard 2000 Preservative EPA Reg. No. 6836-322 EPA Stamped Label 8-15-11

600000

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.

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EPA Stamped Label 8-15-11
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(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 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.

(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.

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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 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 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 (Not for Use in California)

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 and duration of doses will vary with the individual systems and must be established through experience.

Water Floods

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 2,000 to 7,000 ppm Dantogard 2000 (1.7 to 59 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.

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Subsequent Treatment:

Once control has been achieved, add 2,000 – 7,000 ppm Dantogard 2000 (1.7 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 750 – 2,000 ppm (0.6 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 1,000 – 7,000 ppm Dantogard 2000 (3.5 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 1,000 - 5,000 ppm Dantogard 2000 (3.5 to 17.7 gallons Dantogard 2000 per 100 barrels of fluid) to the formulation to be preserved.

Hydrotesting

Water used to hydrotest pipelines or vessels must contain 500 - 7,000 ppm Dantogard 2000 (0.4 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

Individual injection wells must be treated with 2,000 - 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 1,500 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 2,000- 10,000 ppm Dantogard 2000 (1.7 to 8.4 gallons Dantogard 2000 per 1,000 gallons flood water) for 4 – 6 hours based on flow rates. Repeat as necessary until control is achieved.

Subsequent Treatment:

Once control has been achieved, add 1,500 - 5,000 ppm Dantogard 2000 (1.3 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 750 - 2,500 ppm (0.6 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 3,000 - 14,000 ppm (0.3 to 1.2 gallons Dantogard 2000 per 100 gallons water) depending on the length of the pipeline and saverity of biofouling.

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