



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 27, 2016

Kathryn Rosario
Regulatory Assurance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Notification per PRN 98-10 – Updating the label to include the product
Name: Datogard™ 2000 Preservative thought-out the label.
Product Name: DANTOGARD™ 2000 PRESERVATIVE
EPA Registration Number: 6836-322
Application Date: June 28, 2016
Decision Number: 519115

Dear Ms. Rosario,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

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Sincerely,

A handwritten signature in blue ink, consisting of several overlapping, fluid strokes that are difficult to decipher as specific text.

for

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Notification Label

DANTOGARD™ 2000 PRESERVATIVE

NOTIFICATION

6836-322

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/27/2016

PRESERVING YOUR CONFIDENCE IN THE NEW MILLENNIUM

Contents: LIQUID

Active Ingredients:

1,3-Bis (hydroxymethyl)-5,5-dimethylhydantoin	33.2%
Hydroxymethyl-5,5-dimethylhydantoin	31.5%
Other Ingredients	35.3%
Total.....	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]

**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 face shield 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 ¼ 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.

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.

DANTOGARD 2000 PRESERVATIVE preserves and aids in the control of the growth of bacteria 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 fluids¹ 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.

Oil Field and Petrochemical Operations

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

DANTOGARD 2000 PRESERVATIVE 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 PRESERVATIVE** 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 Floods¹

DANTOGARD 2000 PRESERVATIVE 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 PRESERVATIVE** (0.10 to 5.9 gallons **DANTOGARD 2000 PRESERVATIVE** 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 PRESERVATIVE** (0.10 to 5.9 gallons **DANTOGARD 2000 PRESERVATIVE** per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Continuous treatment:

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

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

DANTOGARD 2000 PRESERVATIVE must be added to these fluids at a point where uniform mixing will occur. Add 100 – 7,000 ppm **DANTOGARD 2000 PRESERVATIVE** (0.35 to 24.7 gallons **DANTOGARD 2000 PRESERVATIVE** 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 PRESERVATIVE** (0.35 to 17.7 gallons **DANTOGARD 2000 PRESERVATIVE** per 100 barrels of fluid) to the formulation to be preserved.

Hydrotesting¹

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

Gas Storage Wells and Systems¹

Individual injection wells must be treated with 120 – 7,000 ppm **DANTOGARD 2000 PRESERVATIVE**. Injections must be repeated as needed to maintain control. Individual drips must be treated with a sufficient quantity of **DANTOGARD 2000 PRESERVATIVE** to produce a concentration of 120 to 5,000 ppm **DANTOGARD 2000 PRESERVATIVE** 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 PRESERVATIVE 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 PRESERVATIVE** 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 PRESERVATIVE** (0.10 to 8.4 gallons **DANTOGARD 2000 PRESERVATIVE** 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 PRESERVATIVE** (0.10 to 4.2 gallons **DANTOGARD 2000 PRESERVATIVE** per 1,000 gallons flood water) to the system weekly, or as needed to maintain control.

Continuous treatment:

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

Pipeline Pigging and Scraping Operations

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

¹ Not for Use in California