

6836-116

12/30/2014

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 30, 2014

Ms. Leigh Ann Richardson
Senior Regulatory Associate
Lonza, Inc.
1200 Bluegrass Lakes Parkway
Alpharetta, GA 30004

Subject: Label Notification per PRN 98-10 – Adding Optional Marketing
Claims and Adding a Website for More Information.
Product Name: **Dantobrom S**
EPA Registration Number: **6836-116**
Application Date: December 3, 2014
Decision Number: 498057

Dear Ms. Richardson:

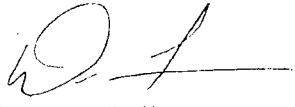
The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls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

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

On Page Four of the current Product Label, it was noted a website addition: LeisureTimeSpa.com. If you wish to retain a reference to the Company's Website on your Product Label, then please be aware that such a reference transforms the Website into labeling under the Federal Insecticide Fungicide and Rodenticide Act see 2 (p) (2) and then the Website is subject to review by the Agency. If the Website content is false or misleading, the Product would be misbranded and its sale or distribution unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 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. Although EPA has not yet determined the extent to which it will routinely review Company Websites, if the Agency finds or it is brought to our attention that a Website contains false or misleading statements or claims substantially differing from claims approved through the registration process, the Website may be referred to the EPA's Office of Enforcement and Compliance Assurance.

If you have any questions, you may contact Killian Swift at 703-308-6346 or via email at Swift.Killian@epa.gov.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'D Fuller', with a horizontal line extending to the right.

Demson Fuller,
EPA Product Manager 32, Regulatory Management Branch II
Antimicrobials Division 7510P

Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

{Items in braces {AAA} are for information purposes and will not appear on final label}

DANTOBROM™ S

NOTIFICATION

Date Received: _____
Reviewed By: _____

December 29, 2014

Killian Swift

BROMINATING DISINFECTANT FOR [SPAS][,] [HOT TUBS] [AND] [POOLS]

[Step 2 – Maintain]

Active Ingredients:

1-bromo-3-chloro-5,5-dimethylhydantoin	54.2%
1,3-dichloro-5,5-dimethylhydantoin	28.9%
1,3-dichloro-5-ethyl-5-methylhydantoin	15.9%
Other Ingredients:	1.0%
Total:	100.0%

Total Available Halogen as Bromine: 141%

[and/or]

Total Available Halogen as Chlorine: 62.8%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See [side] [back] [right] [left] panel for additional Precautionary Statements and First Aid

EPA Reg. No. 6836-116

EPA Est. No. 6836-PA-01

Net Weight: (as indicated on the container)

[DOT Symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Emergency Contact Number: (_____)



Dantobrom S

EPA Reg. No. 6836-116

EPA Stamped Label 3/7/11 w/ 2/27/12, 5/8/12, 7/30/12, 1/23/13, 3/7/13, & 7/7/14 Notifications

Proposed label 12/03/14

Note to reviewer:

[Items in brackets [AAA] are optional and may/may not be included on final label]

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: HIGHLY CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if swallowed. Do not take internally. Irritating to nose and throat. Avoid breathing dust. Use with adequate ventilation. Do not get into eyes, on skin or on clothing. Wear protective clothing, chemical resistant gloves and protective eyewear (goggles, face shield or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

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.

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 person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish.

{Note to reviewer: If container size is 50 lbs. or larger, the following statements will also be used:}

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.

PHYSICAL AND CHEMICAL HAZARDS

CHEMICAL HAZARD. STRONG OXIDIZING AGENT. Mix only with water. Use clean dry utensils. Do not add this product to any dispensing device containing remnants of any other product. Such use may cause a violent reaction leading to fire or explosion. Contamination with moisture, organic matter, or other chemicals may start a chemical reaction with generation of heat, liberation of hazardous gases, and possible generation of fire and explosion. In case of contamination or decomposition, do not re-seal container. If possible, isolate container in open air or well-ventilated area. Flood with large volumes of water if necessary.



Note to reviewer:

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{Note to reviewer: The following is considered optional marketing language:}

Total available halogen content as bromine..... 140%

- o Tablet shape fits all floaters
- o High level of active halogen (bromine)
- o Improved bather comfort
- o No bleaching of hair or bathing suits
- o Doesn't reduce pH or affect hardness
- o [Very] low odor
- o Low dust tablets
- o Ideal for [spa] [/] [hot tub] sanitizing
- o Works with inline of floating feeders
- o Ideally suited for floater type feeders
- o Fits all floaters
- o Creates soft water feel
- o No chlorine odor
- o Effective pool sanitizer
- o Sanitizer
- o Disinfects pool water
- o Step 1: Balance
- o Step 2: Sanitize {sanitize would be the highlighted step}
- o Step 3: Shock
- o Step 4: Prevent Algae
- o Brominating Sanitizer

hth spa product guide

Maintain

Step 1

Step 2

Step 3

Enhance

Prevent



Dantobrom S

EPA Reg. No. 6836-116

EPA Stamped Label 3/7/11 w/ 2/27/12, 5/8/12, 7/30/12, 1/23/13, 3/7/13, & 7/7/14 Notifications

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[Brand or POOLIFE] 3-Step System]

{The "[Brand or POOLIFE] 3-Step System" below may be placed on the label to allow easy product identification by consumers.}

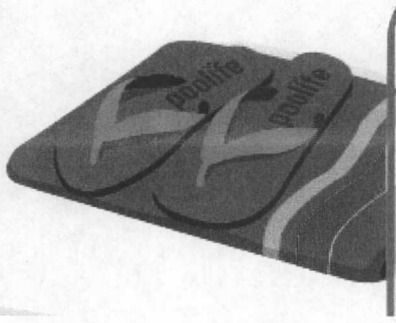
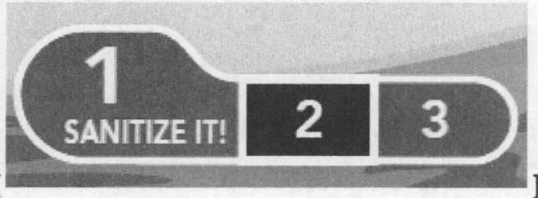
[[Brand or POOLIFE] 3-Step System:

[Step] 1 [Sanitize [It!]]

[Step] 2 [Shock [It!]]

[Step] 3 [Defend [It!]]

{Graphic rendering of the above 3 steps}



{Optional language for use on a kit label that contains this product:}

Simple Spa Care

Everything you need to take care of your spa

WELCOME TO LEISURE TIME® SPA CARE

As a new spa owner, you'll love how easy Leisure Time® products make caring for your investment. And if you've had a spa before, you'll appreciate how simple Leisure Time® products are to use. After all, you want your spa to enhance your leisure time, not consume it.

Inside is everything you need to start up your spa and keep it running with clean, clear, luxurious water. Plus, there are test strips and a spa care guide included to help answer any questions you have about how to care for your spa water. With the Leisure Time® spa Simple Spa Care® Program, you'll spend more time in your spa than maintaining it!

LeisureTimeSpa.com

For more information on [this or other] Leisure Time® products, please visit [our website at] LeisureTimeSpa.com.

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[WHY YOU SHOULD USE THIS PRODUCT]

DANTOBROM S is a form of brominating hydantoin for [spas][,] [hot tubs] [and] [pools]. It is easily adapted to many erosion feeders used to automatically treat both commercial and residential [spas][,] [hot tubs] [and] [pools].

When used as directed, **DANTOBROM S** will disinfect [spa][,] [hot tub] [and] [pool] water, keeping it clean, clear and free of odor. **DANTOBROM S** gives the effectiveness of chlorine without the chlorine odor. Proper sanitary practices require [changing spa water at a minimum of every 30 days] [and] [properly monitoring pool water conditions.]

DIRECTIONS FOR USE

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

DANGER: Do not mix this product in concentrated form with any other chemicals. Do not add other chemicals to the feeding device when using this product. A violent reaction leading to fire and/or explosion could result.

Re-entry into treated [pools] [and] [spas] is prohibited above levels of 8 ppm due to risk of bodily injury.

[SPA DIRECTIONS]

NOTE: Before using **DANTOBROM S** in your spa or hot tub for the first time, add 1/2 ounce of sodium bromide per 100 gallons of water to establish a 30 ppm bromide concentration. Also, add sodium bromide at this dosage whenever the spa or hot tub is drained and refilled. The bromide addition ensures immediate establishment of an all-bromide system, eliminates chlorinous odors and maximizes skin and eye comfort.

SPA OR HOT TUB START UP:

To start up a new spa or hot tub, or one recently drained, clean all surfaces, backflush or clean the filter, chemically balance the calcium hardness and total alkalinity, treat for metals if present (iron, copper and manganese), and adjust the pH to 7.2 - 7.8.

Using a suitable feeder adjusted according to the manufacturer's directions, add **DANTOBROM S** to maintain an active bromine concentration of 2 to 4 ppm in residential spas and 3 to 6 ppm in commercial spas. Use a reliable test kit to monitor for bromine regularly.

DANTOBROM S usage will typically vary from 0.015 to 0.10 pound for every 300 gallons of spa water to maintain the recommended bromine concentration range.

The presence of organic debris, high bather use and other factors may require a higher dosage.

SUPEROXIDATION:

Water soluble, non-filterable wastes can accumulate in spa or hot tub water and cause dull or cloudy water and can stimulate algal growth. Superoxidation or superchlorination with a suitable oxidizing shock treatment must be done on a regular basis to remove these wastes and maintain clear sparkling water. [Suitable oxidizing agents are those based on calcium hypochlorite, lithium hypochlorite, sodium hypochlorite or potassium peroxymonopersulfate.]

Note to reviewer:

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[POOL DIRECTIONS]

TO START UP A NEW POOL, OPEN A POOL FOR THE SEASON OR CONVERT FROM A CHLORINE BASED PROGRAM:

Backflush or clean the filter, chemically balance the calcium hardness and alkalinity and adjust pH to 7.2 to 7.8. Superoxidate to obtain a residual of 10 to 20 ppm available bromine [5 to 10 ppm available chlorine] as determined by a suitable test kit. Swimming may begin when the bromine level drops below 8 ppm.

When the bromine level drops below 1 to 3 ppm, add 0.2 to 2.0 ounces of **DANTOBROM S** per 1000 gallons daily, or as needed. Use a suitable feeder device adjusted according to the manufacturer's instructions so as to maintain 1 to 3 ppm available bromine. Use a reliable test kit to monitor for bromine regularly. Maintain the pool water pH between 7.2 and 7.8.

High temperatures, the presence of organic debris, high bather use and other factors may require more frequent treatments.

SUPEROXIDATION:

Water soluble, non-filterable wastes can accumulate in pool water and cause dull or cloudy water and can stimulate algal growth. Superoxidation or superchlorination with a suitable oxidizing shock treatment must be done weekly or bi-weekly, after extremely heavy bather loads or heavy rain storms. [Suitable oxidizing agents are those based on calcium hypochlorite, lithium hypochlorite, sodium hypochlorite or potassium peroxymonopersulfate.]



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{Note to reviewer: For Nonrefillable Containers, Household/Residential Uses; Product is non-dilutable solid}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children in a cool, dry, well-ventilated area. Do not store at temperatures above 100°F. Nonrefillable container. Do not reuse or refill this container. Discard empty container in trash or offer for recycling if available.

{Note to Reviewer/Subregistrant: If both nonrefillable and refillable container storage and disposal directions appear on the final label, a sticker must be added to the container stating if it is a nonrefillable or refillable container. Also, the following statement must be included directly above the storage and disposal directions on the final label:}

See the sticker on the [front] [back] [side] [top] of the container to determine if it is nonrefillable or refillable.

{Note to reviewer: For Nonrefillable Containers, Commercial/Industrial/Institutional Uses, Product is non-dilutable solid}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Keep container tightly closed. Store in a cool, dry, well-ventilated place. Do not store in direct sunlight. Do not store at temperatures above 100°F.

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 the label instructions contact your State pesticide or environmental control agent or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container.

{Metal and plastic containers:} Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate or burn if allowed by State and local authorities. If burned, stay out of smoke. If not tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{Metal containers only:} DO NOT cut or weld metal containers.

{Fiber drums and liners:} Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Offer for recycling, if available or dispose of liner and drum in a sanitary landfill or incinerate if allowed by State and local authorities.

{Bulk Bag/Super Sack Container:} Completely empty bag into application equipment by shaking and tapping sides and bottom to loosen clinging particles. If not emptied in this manner, the bag may be considered an acute hazardous waste and must be disposed in accordance with local, state and federal regulations. When completely empty, offer for recycling if available or dispose of bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{Tote Container:} Empty tote container must be returned to a tote collection agent.



Note to reviewer:

{Items in brackets [AAA] are optional and may/may not be included on final label}

{Items in braces {AAA} are for information purposes and will not appear on final label}

{Note to reviewer: For Refillable Containers, Commercial/Industrial/Institutional Uses, Product is non-dilutable solid}

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Refillable container. Refill this container with (this product) only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller.

{Metal and plastic containers:} Attach tamper evident devices [seals] to all openings, except vents, and return to the manufacturer for refilling.

{Tote Containers:} Empty tote container must be returned to a tote collection agent.

{Plastic drums and liners:} Attach tamper evident devices [seals] to all drum openings, except vents, and return the drum to the manufacturer for refilling.

PESTICIDE STORAGE: Keep container tightly closed. Store in a cool, dry, well-ventilated place. Do not store in direct sunlight. Do not store at temperatures above 100°F.

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 the label instructions contact your State pesticide or environmental control agent or the hazardous waste representative at the nearest EPA regional office for guidance.

FINAL CONTAINER DISPOSAL: Cleaning the container before final disposal is the responsibility of the person disposing of the container.

{Metal and plastic containers:} To clean the container before final disposal empty remaining contents from container for use according to use directions and triple rinse promptly after emptying. Triple rinse (or equivalent).

{Tote Containers:} To clean the container before final disposal empty remaining contents from container for use according to use directions and triple rinse promptly after emptying. Triple rinse (or equivalent). For additional container disposal information, contact product supplier.

{Plastic drums and liners:} Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Offer for recycling, if available or dispose of liner in a sanitary landfill or incinerate if allowed by State and local authorities.

