

6836-116

3/7/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


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

March 7, 2008

 OFFICE OF
 PREVENTION, PESTICIDES
 AND TOXIC SUBSTANCES

 Georgia Anastasiou
 Agent for Lonza, Inc.
 c/o Lewis & Harrison
 122 C St., NW Suite 740
 Washington, DC 20001

 Subject: Dantobrom S
 EPA Registration No. 6836-116
 Application Date: February 19, 2008
 Receipt Date: February 21, 2008

Dear Ms. Anastasiou:

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

Proposed Notification

- Addition of non-FIFRA marketing text

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6345.

Sincerely,

 Wanda Y. Henson
 Product Reviewer (32)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

CONCURRENCES

YMBOL	7510P	7510P						
URNNAME	Ek Berg	Henson						
ATE	3/7/08	3/7/08						

**EPA**

United States

Environmental Protection Agency

Washington, DC 20460

☐ Registration☐ Amendment:☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number

6836-116

2. EPA Product Manager

Emily Mitchell

3. Proposed Classification

4. Company/Product (Name)

Dantobrom S

PM#

32☒ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

Lonza, Inc.**90 Boroline Rd.****Allendale, NJ 07401****PLEASE SEND ALL CORRESPONDENCE TO****"CONTACT POINT" LISTED BELOW**☐ Check if this is a new address6. **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☐ Amendment - Explain below.☐ Resubmission in response to Agency letter dated _____☒ Notification - Explain below.☐ Final printed labels in response to Agency letter dated _____☐ "Me Too" Application☐ Other - Explain below**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)**Application for Notification to Add Marketing Text**

Please read cover letter for details

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes*☐ No

Unit Packaging

☐ Yes☐ No

Water Soluble Packaging

☐ Yes☐ No

2. Type of Container

☐ Metal☐ Plastic☐ Glass☐ Paper☐ Other (Specify)***Certification must be submitted**

If "Yes"

Unit Packaging wgt.

No. per

container

If "Yes"

Package wgt.

No. per

container

3. Location of Net Contents Information

☐ Label☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph☐ Paper glued☐ Stenciled☐ Other _____**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: **Georgia Anastasiou, Lewis & Harrison, LLC,**
122 C Street NW, Ste. 740, Washington, DC 20001Title: **Agent for Lonza, Inc.**Telephone No. (Include Area Code): **202-393-3903 x19****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

3. Title

Agent for Lonza, Inc.

4. Typed Name

Georgia Anastasiou

5. Date

February 19, 20086. Date Application Received
(Stamped)

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LEWIS & HARRISON

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

Consultants in Government Affairs

February 19, 2008

HAND DELIVERED

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard, Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202

ATTENTION: Emily Mitchell
Product Manager (32)

SUBJECT: Lonza, Inc.
Dantobrom S (EPA Reg. No. 6836-116)
Application for Notification per PR-NOTICE 98-10

Dear Ms. Mitchell:

As agent for Lonza, Inc., I am submitting a notification per PR Notice 98-10 for the product, **Dantobrom S (EPA Reg. No. 6836-116)**. The purpose of this notification is to add the following marketing text to the label:

- (Step 2 – Maintain)
- (Very)low odor
- Fits all floaters
- hth spa product guide, Maintain, Step 1, Step 2, Step 3, Enhance, Prevent

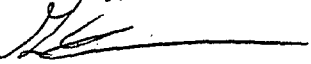
Notification for an Antimicrobial Product in Accordance With PR Notice 98-10 This notification is consistent with the provisions of PR Notice 98-10 EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand 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 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Enclosed please find the following documents in support of this amendment:

- a) Application for Pesticide Amendment;
- b) One (1) copy of the proposed product with changes highlighted;
- c) Two (2) copies of the proposed product label; and,
- d) CD which contains a PDF copy of the proposed product label.

Thank you for your assistance with this submission. If you have any questions please feel free to contact me at 202-393-3903 ext. 19 or georgia@lewisharrison.com.

Sincerely,


Georgia Anastasiou
Agent for,
Lonza, Inc.

cc: Robert Sloan (LONZA, Inc.)

cc: Robert Sloan (LONZA, Inc.)

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DANTOBROM® S

BROMINATING DISINFECTANT FOR SPAS, HOT TUBS AND POOLS

(Step 2 – Maintain)

Active Ingredients:

1-bromo-3-chloro-5,5-dimethylhydantoin	60.0%
1,3-dichloro-5,5-dimethylhydantoin	27.4%
1,3-dichloro-5-ethyl-5-methylhydantoin	10.6%
Other Ingredients:	2.0%
Total:	100.0%

Available bromine	39.2%
Available chlorine	44.4%

KEEP OUT OF REACH OF CHILDREN

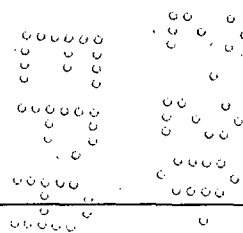
DANGER

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)

Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Emergency Contact Number: (_____)



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. 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: The following is considered optional marketing language:)

Total available halogen content as bromine 140%

- Tablet shape fits all floaters
- High level of active halogen (bromine)
- Improved bather comfort
- No bleaching of hair or bathing suits
- Doesn't reduce pH or affect hardness
- (Very) low odor
- Low dust tablets
- Ideal for spa / hot tub sanitizing
- Works with inline of floating feeders
- Ideally suited for floater type feeders
- Fits all floaters

hth spa product guide Maintain Step 1 Step 2 Step 3 Enhance Prevent
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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.

SPA DIRECTIONS

NOTE: Before using **DANTOBROM S** in your spa or hot tub for the first time, add ½ 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 should 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.

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 6 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 should 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.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

- Do not store in direct sunlight.
- Do not store at temperatures above 100°F.
- Do not store on side. Avoid creasing or impacting of side walls.
- Keep container tightly closed.
- Store in a cool, dry, well-ventilated place that is inaccessible to children.
- Do not store at elevated temperatures.

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:

(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.

(Fiber drums and liners): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Then dispose of liner and drum in a sanitary landfill or incinerate if allowed by State and local authorities. Do not reuse empty drum or liner.