

6836-116

5/8/2012

1/11



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

MAY - 8 2012

Joanna Holcombe  
Lonza Inc.  
90 Boroline Road  
Allendale, NJ 07401

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Subject: Dantobrom<sup>TM</sup> S  
EPA Registration No.: 6836-116  
Notification Date: 04/26/2012  
EPA Receipt Date: 04/30/2012

Dear Ms. Holcombe,

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

**Proposed Notification**

- Addition of optional signal word "Peligro," marketing/sticker language and brackets

**General Comments**

Based on a review of the submitted materials, your notification for additional storage and disposal language is acceptable.

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 [campbell-mcfarlane.jacqueline@epa.gov](mailto:campbell-mcfarlane.jacqueline@epa.gov) or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at [carl.jaclyn@epa.gov](mailto:carl.jaclyn@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 black ink, appearing to read "Jacqueline Campbell-McFarlane".

Jacqueline Campbell-McFarlane  
Product Manager (34)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

<b>EPA</b>	United States	<input type="checkbox"/> Registration	OPP Identifier Number
	Environmental Protection Agency	<input type="checkbox"/> Amendment	
	Washington, DC 20460	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number <b>6836-116</b>	2. EPA Product Manager <b>Monisha Harris</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Dantobrom S</b>	PM# <b>32</b>	
5. Name and Address of Applicant (Include ZIP Code) <b>Lonza Inc. 90 Boroline Road Allendale, NJ 07401</b>	6. <b>Expedited Review.</b> 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	
<input type="checkbox"/> Check if this is a new address		

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 make some marketing language optional, to add language for final labels containing both refillable and nonrefillable storage and disposal language, etc. 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: Joanna Holcombe Date: 4-26-12

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	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
	If "Yes" Unit Packaging wgt.      No. per container	If "Yes" Package wgt.      No. per container		<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container  <b>various</b>		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input checked="" type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input checked="" 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 <b>Joanna Holcombe</b>	Title <b>Sr. Commercial Regulatory Services Associate</b>	Telephone No. (Include Area Code) <b>201-316-9297</b>
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  <b>(Stamped)</b>
2. Signature <u>Joanna Holcombe</u>	3. Title <b>Sr. Commercial Regulatory Services Associate</b>	
4. Typed Name <b>Joanna Holcombe</b>	5. Date <u>4-26-12</u>	



Via FedEx

Ms. Monisha Harris, PM-32  
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

Joanna Holcombe  
Lonza Microbial Control  
Commercial Regulatory Services

Tel 678-627-2336  
joanna.holcombe@lonza.com

April 26, 2012

**SUBJECT: Dantobrom S, EPA Reg. No. 6836-116  
Application for Label Notification**

Dear Ms. Harris:

I am submitting an application to make the following changes to the Dantobrom S, EPA Reg. No. 6836-116, product label:

All Pages: Add footnote indicating use of brackets for optional language and braces for informational statements.

Pages 1 & 3: Made some of the marketing language optional. All language to be considered optional has been enclosed in brackets, which have been highlighted.

Page 1: Added an optional signal word in Spanish.

Pages 4 & 5: Bromine reentry statement change  
We believe that the condition that EPA requested in the 8/18/09 comments letter for 6836-116 (letter attached) was incorrect. The Statement "Re-entry into treated pools is prohibited above levels of 4 ppm due to risk of bodily injury" was required by EPA. We believe that the statement should be "Re-entry into treated [pools] [and] [spas] is prohibited above levels of 8 ppm due to risk of bodily injury". Unfortunately, the typo has been carried through one Amendment and one Notification. Another EPA registration, "Bioguard Master BCDMH" (EPA Reg. 5185-420) has the 8 ppm re-entry statement throughout the label (see attached Bioguard label dated Sept. 27, 2011). We believe EPA mixed up the level for chlorine, however, this is a bromine registration. Having a limit of 4 ppm for bromine doesn't make sense from a chemistry perspective. The levels of chemicals are typically measured in ppm (i.e. mg/L) units. Since bromine is ~ twice as heavy as chlorine (bromine molecular weight = 79.9 g/mole, Chlorine = 35.5 g/mole), that means that you are limiting the concentration of bromine **atoms** to half the level allowed for chlorine. This is unduly restrictive. We believe that this can be corrected by Notification.

2/2, April 26, 2012, Dantobrom S, EPA Reg. No. 6836-116

Page 6: Added note to reviewer and referral statement regarding final labels with both nonrefillable and refillable storage and disposal directions. A sticker will be applied to the container that indicates which kind of container it is, and "See the sticker on the [front] [back] [side] [top] of the container to determine if it is nonrefillable or refillable." will appear above the storage and disposal directions.

Please find the enclosed documents in support of this notification:

- Application for Notification;
- Copy of the "Bioguard Master BCDMH" (EPA Reg. 5185-420) label;
- Certification with Respect to Label Integrity;
- CD with label; and
- 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 678-627-2336.

Sincerely,  
Lonza Inc.

Joanna Holcombe  
Sr. Commercial Regulatory Services Associate

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# DANTOBROM™ S

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

**NOTIFICATION**  
Date Reviewed: 5/8/12  
Reviewed By: J. Cat

[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]**

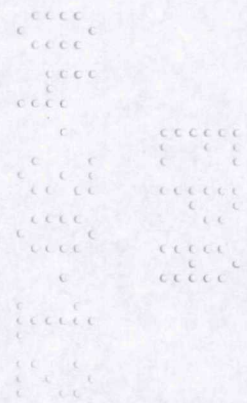
See [side] [back] [right] [left] panel for additional Precautionary Statements and First Aid

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: (\_\_\_\_\_)





{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 or floating feeders
- o Ideally suited for floater type feeders
- o Fits all floaters

hth spa product guide

Maintain

Step 1

Step 2

Enhance

Prevent



**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 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.

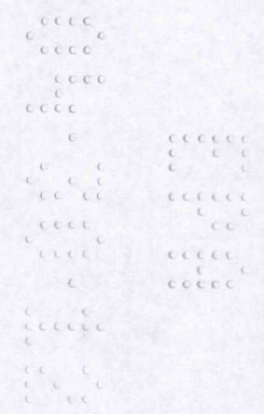
Using a suitable feeder adjusted according to the manufacturer's directions, add **DANTOBROM S** to maintain an active bromine concentration of 2 to 4 ppm in residential spas and 3 to 6 ppm in commercial spas. Use a reliable test kit to monitor for bromine regularly.

**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 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 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.



{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: 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.

