



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6836-287

9/27/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 27 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Joann Holcombe
Senior Commercial Regulatory Services Associate
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Dantochlor TBS-4
EPA Reg. No. 6836-287
Application Dated: September 6, 2011
Receipt Date: September 7, 2011

Dear Ms. Holcombe:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Label revision to update household/residential Storage and Disposal Statements per PR Notice 2007-4
Additional minor label revisions

Comments:

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

This application for notification to revise the label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact me at harris.monisha@epa.gov or call (703) 308-0410.

Sincerely,

[Handwritten signature of Monisha Harris]

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

Table with 8 columns and 3 rows for tracking approvals. Rows are labeled SYMBOL, SURNAME, and DATE.

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<b>EPA</b> Environmental Protection Agency Washington, DC 20460	Uni states <input type="checkbox"/> Registrati <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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**Application for Pesticide - Section I**

1. Company/Product Number <b>6836-287</b>	2. EPA Product Manager <b>Wanda Henson</b>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <b>Dantochlor TBS-4</b>	PM# <b>32</b>	
5. Name and Address of Applicant (Include ZIP Code) Lonza Inc. 90 Boroline Road Allendale, NJ 07401  <input type="checkbox"/> Check if this is a new address		6. 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**

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Other - Explain below
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**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**\*Not Subject to PRIA\***

**Label Notification to update Storage and disposal language per PR Notice 2007-4, etc. Please 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: 9-2-11

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt.      No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt.      No. per container	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1 oz. - 25 oz.		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  (Stamped)
2. Signature 	3. Title <b>Sr. Commercial Regulatory Services Associate</b>	
4. Typed Name <b>Joanna Holcombe</b>	5. Date <b>9-2-11</b>	

3 7 8



Via FedEx

Lonza Inc  
Allendale  
90 Boroline Road  
Allendale, NJ 07401, USA

Ms. Wanda Henson, PM-32  
Document Processing Desk (PRN)  
Office of Pesticide Programs (7504P)  
US Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2227 S. Crystal Drive  
Arlington, VA 22202

**Joanna Holcombe**  
Lonza Life Science Ingredients  
Commercial Regulatory Services

Tel 201-316-9297  
Fax 201-696-3470  
joanna.holcombe@lonza.com

September 2, 2011

**SUBJECT: Dantochlor TBS-4, EPA Reg. No. 6836-287  
Application for Label Notification in Response to PR Notice 2007-4**

Dear Ms. Henson:

I am submitting an application to update the storage and disposal language for the abovementioned product. The language has been updated according to PR Notice 2007-4 for ready-to-use products. Dantochlor TBS-4 is not currently in production. Therefore, we are unable to send CRP information for household/residential use to the Agency for review. As explained on the enclosed "Certification of Child-Resistant Packaging," Lonza will submit that information should a distributor be found.

Additional changes have been made to the label:

- Update pathogen nomenclature to Salmonella enterica;
- Add optional Spanish signal word;
- Add optional language and/or placeholders for DOT symbols, Country of origin, Manufactured in, and Barcode;
- Add Notes to Reviewer regarding marketing language;
- Add note to reviewer and the following optional Spanish language statement and English translation:  
*Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*
- Add optional diagram which shows tablet placement in the tank.

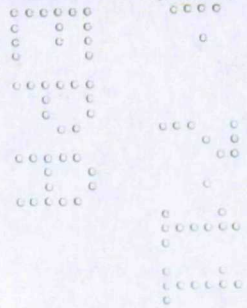
Please find the enclosed documents in support of this notification:

- Application for Notification;
- Certification of Child-Resistant Packaging; 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 201-316-9297.

Sincerely,  
Lonza Inc.

  
Joanna Holcombe  
Sr. Commercial Regulatory Services Associate



# DANTOCHLOR TBS-4

- [In-Tank] Sanitizer for Homes, Schools, and Hospitals
- [In-Tank] Automatic Toilet Bowl Cleaner [and Sanitizer]
- Sanitizes Toilet Bowl Water [After Each Flush]
- Kills 99.9% Of Bacteria In Toilet Bowl Water [After Each Flush]
- Cleans and Deodorizes With Every Flush
- [Helps] Keep Your Toilet Bowl Fresh and Clean
- Recommended for frequently flushed toilets
- [Each tablet] Kills bacteria for 4 months
- Kills E. coli
- Kills Staphylococcus aureus [staph]
- Kills Salmonella **enterica** [salmonella]
- Kills Enterococcus faecalis [strep]
- Kills Pseudomonas aeruginosa [pseudomonas]
- Kills Candida albicans [candida]
- Kills common household bacteria
- Kills bathroom bacteria
- Kills many odor-causing bacteria

**NOTIFICATION**  
 Date Reviewed: 9/27/2011  
 Reviewed By: M. Stevens

Active Ingredients:

1,3-dichloro-5,5-dimethylhydantoin .....	81.1%
1,3-dichloro-5-ethyl-5-methylhydantoin .....	16.1%
Inert Ingredients: .....	2.8%
Total: .....	100.0%

Minimum Available Chlorine 68.0%

**KEEP OUT OF REACH OF CHILDREN**

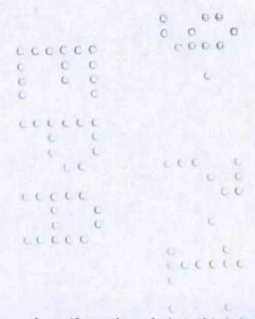
**DANGER [PELIGRO]**

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

EPA Reg. No. 6836-287  
 EPA Est. No. 6836-PA-01  
 Net Weight: 100 grams [3.5 oz.] [each]

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

Manufactured by:  
 Lonza Inc.  
 90 Boroline Road  
 Allendale, NJ 07401



**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Highly corrosive. May be fatal if swallowed. **DO NOT TAKE INTERNALLY.** Causes eye and skin damage. Irritating to nose and throat. Avoid breathing dust. Do not get into eyes, on skin or clothing. Wear rubber gloves when handling and wash thoroughly after handling.

**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 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.

**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 treatment advice. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.

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

**PHYSICAL AND CHEMICAL HAZARDS**

**CHEMICAL HAZARD: STRONG OXIDIZING AGENT.** Keep away from heat or flame. Mix only with water.

{Note to Reviewer: the following is considered optional marketing language:}

- Antibacterial
- Anti-Bacterial
- Antibacterial Toilet Bowl Cleaner
- Anti-Bacterial Toilet Bowl Cleaner
- Bleach automatic toilet bowl cleaner
- Chlorine clear with Bleach
- Sanitizing Formula Cleans & Deodorizes
- Cleans & Deodorizes With Bleach
- Keeps Water Crystal Clear
- Easy To Use - Just Drop In Tank
- Easy to Use – No Mess
- Kills 99.9% of bacteria for 4 months[!] In Toilet Bowl Water After Each Flush
- Not Harmful to Plumbing or Septic Systems [when used as directed]
- Leaves bowl sanitary
- Makes cleaning easy
- Controls odor-causing bacteria in the bowl water
- Controls the growth of bacteria that cause odors
- Controls odors caused by odor-causing bacteria
- Kills odor causing bacteria
- Kills bacteria and [helps] prevents stains
- Kills and prevents the growth of bacteria
- Fights tough stains
- Keeps your toilet bowl stain-free
- Continuous [real bleach] cleaning and deodorizing
- Continuous cleaning action
- Continuous sanitizing action
- Continuous cleaning and sanitizing action
- No Mess in tank
- Bleach cleaning
- For colored toilets
- For use with many other blue drop-in[s] [tablets]
- Actual size
- Bonus Size
- Great Value
- [Each] [Tablet] Cleans up to 4 months
- Concentrated to clean up to 4 months
- Concentrated [formula] [tablet] to sanitize [and clean] for up to 4 months
- Cleans [and sanitizes] with every flush [for up to 4 months]
- Sanitizes up to 4 months
- Cleans and sanitizes up to 4 months
- Cleans and deodorizes with the power of chlorine [bleach]
- Cleans up to 4 times longer than [30 day tablets] [other tablets] [in tank] automatic toilet bowl cleaners
- [Concentrated] Longest lasting automatic toilet bowl cleaner
- Up to 12 flushes a day
- Circulates [concentrated] cleaners and sanitizers directly into [the] [toilet] bowl
- Circulates the long lasting cleaning power of Dantochlor TBS-4 directly into the bowl for [continuous] [up to 4 months] of sanitization and cleaning
- [Helps] keep[s] your bathroom Fresh, Clean, and Sanitary
- Repels tough stains
- [Concentrated formula] Repels [prevents] mineral and other stains [from forming]
- Cleans and Freshens[!]
- Drop-in
- [Contains] No phosphates or phosphorous compounds

{Note to Reviewer: the following is considered optional marketing language:}

- Time release formula [formulation]
- Formulated to deliver consistent [powerful] cleaning and sanitization for up to 4 months!

{Note to reviewer: The following phrases are for packages that contain two tablets:}

- 2-Pack
- 8 months of sanitization and cleaning [power]!
- Each tablet kills 99% of bacteria for up to 4 months [for a total of 8 months]
- Twin Pack

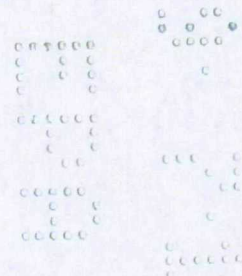
When used as directed, Dantochlor TBS-4 will sanitize toilet bowl water, keeping it clean, clear and free of odor. Dantochlor TBS-4 gives the effectiveness of chlorine without the chlorine odor.

Dantochlor TBS-4 sanitizes toilet bowl water by [killing] [eliminating] 99.9% of bacteria within 15 minutes after each flush. Each tablet sanitizes for 4 months. Eliminates 99.9% of bacteria within 15 minutes after each flush. Each tablet sanitizes the toilet bowl water [within 15 minutes] for up to 4 months.

Questions? Comments? Call (insert telephone number here)

This product contains no phosphates or phosphorous compounds. No mess. Does not harm plumbing or septic tanks [when used as directed]. Concentrated. Leaves bowl 99.9% bacteria free.

Remove tank cover and cut open package.



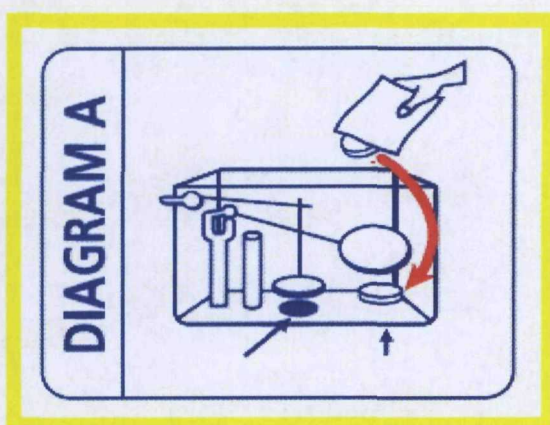
*{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}  
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.]*

**DIRECTIONS FOR USE**

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

To Sanitize, Clean, and Deodorize:

1. Clean toilet bowl thoroughly [including] [even] under the rim.
2. Remove toilet tank top. Hold [one] plastic pouch away from face. Cut [one] pouch open with scissors [on][along] dotted lines [below the crimped edge]. Do not touch tablet[s].
3. Flush toilet. Before tank refills, hold [plastic] pouch over tank and drop only the **Dantochlor TBS-4** tablet into the right rear corner of the tank. [See diagram] Discard plastic pouch and wash hands thoroughly.
4. No removal necessary. Each tablet sanitizes for four months. When tablet has dissolved, [simply] replace with a new tablet. Product should only be used in a toilet that is flushed [regularly] [at least once a week].



*{Note to reviewer: For Nonrefillable Containers, Household/Residential Uses; Ready to Use Product - not a dilutable per PRN 2007-4}*

**STORAGE AND DISPOSAL**

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

