

6836-291

09-27-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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-6
EPA Reg. No. 6836-291
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,

Monisha Harris
Product Manager (S2)

CONCURRENCES					
SYMBOL					
SURNAME					
DATE					

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EPA Environmental Protection Agency Washington, DC 20460	United States <input type="checkbox"/> Registrant <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section 1

1. Company/Product Number 6836-291	2. EPA Product Manager Wanda Henson	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dantochlor TBS-6	PM# 32	
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"/> 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 to update Storage and disposal language per PR Notice 2007-4, etc. Please see cover letter for details.

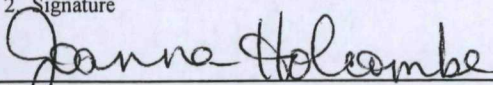
This notification is consistent with the provisions of PR-Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false 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: 9-6-11

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 Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9297
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 Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date 9-6-11	



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 6, 2011

**SUBJECT: Dantochlor TBS-6, EPA Reg. No. 6836-291
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 Note 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.

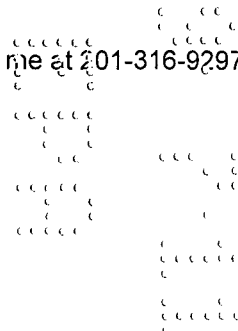
Please find the enclosed documents in support of this notification:

- 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-6

In-Tank Sanitizer for Homes, Schools, and Hospitals

In-Tank Automatic Toilet Bowl Cleaner

Sanitizes Toilet Bowl Water After Each Flush

Kills 99.9% Of [Germs] [Bacteria] In Toilet Bowl

Water After Each Flush

Cleans and Deodorizes With Every Flush

Helps Keep Your Toilet Bowl Fresh and Clean

For frequently flushed toilets

Kills [germs][bacteria] for over 2 ½ months

Kills Escherichia coli [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 [germs][bacteria]

Kills bathroom [germs][bacteria]

Kills many odor-causing [germs][bacteria]

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. 6836-291

EPA Est. No. 6836-PA-01

Net Weight 50 grams

[DOT Symbols]

[Country of origin (insert country)]

[Manufactured in (insert country)]

[Barcode]

NOTIFICATION
Date Reviewed: 9/27/2011
Reviewed By: M. Harris

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 eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

If on Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

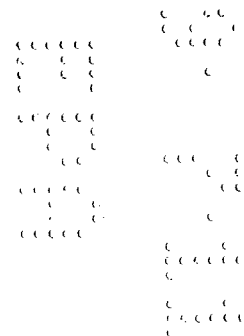
If Inhaled: If not breathing, give artificial respiration, preferably, mouth-to-mouth. Get medical attention.

If Swallowed: Call a doctor or get medical attention. **DO NOT** induce vomiting. Do not give anything by mouth to an unconscious person. Avoid alcohol.

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
- CHLORINE CLEAR with Bleach
- Sanitizing Formula Cleans & Deodorizes
- Cleans & Deodorizes With Bleach
- Keeps Water Crystal Clear
- Easy To Use - Just Drop In Tank
- Kills 99.9% Of [Germs][Bacteria] for over 2 ½ months! In Toilet Bowl Water After Each Flush
- Not Harmful to Plumbing or Septic Systems
- Leaves bowl sanitary
- Makes cleaning easy
- Controls odor-causing [germs][bacteria] in the bowl water
- Controls the growth of [germs][bacteria] that cause odors
- Controls odors caused by odor-causing [germs][bacteria]
- Fights tough stains
- Keeps your toilet bowl stain-free
- Continuous real bleach cleaning and deodorizing
- No Mess in tank
- Bleach cleaning
- For colored toilets
- Great for use with [Can be used with] many other blue drop-in[s] [tablets]

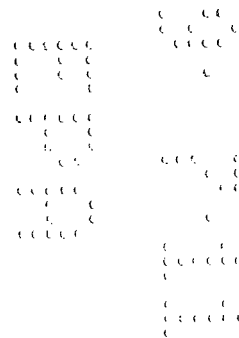
Questions? Comments? Call (insert telephone number here)

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

When used as directed, **Dantochlor TBS-6** will sanitize toilet bowl water, keeping it clean, clear and free of odor. **Dantochlor TBS-6** gives the effectiveness of chlorine without the chlorine odor.

Dantochlor TBS-6 sanitizes toilet bowl water by killing 99.9% of [germs][bacteria] within 15 minutes after each flush. Each tablet sanitizes for over 2½ months. Eliminates 99.9% of [germs][bacteria] within 15 minutes after each flush.

Remove tank cover and cut open package.



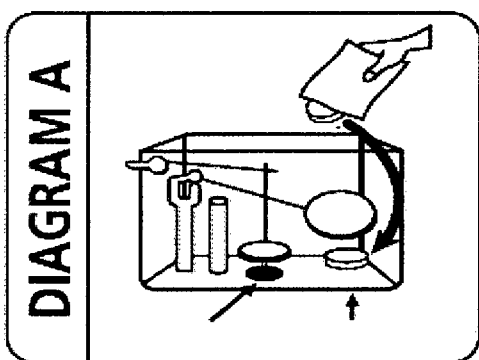
{If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.}
Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. [If you do not understand the label, find someone to explain it to you in detail.] *

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 under the rim.
2. Remove toilet tank top. Hold plastic pouch away from face. Cut pouch open with scissors on dotted lines. **Do not touch tablet.**
3. Flush toilet. Before tank refills, hold plastic pouch over tank and drop only the **Dantochlor TBS-6** 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 2½ months. When tablet has dissolved, replace with a new tablet. Product must be used in a toilet that is flushed regularly.



{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.

