

8-9-2007

6836-288

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

August 9, 2007

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

Subject: Dantochlor TBS-5
EPA Registration No. 6836-288
Application Date: July 20, 2007
Receipt Date: July 20, 2007

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 marketing claims
- Addition of optional language to indicate total weight and for different size packaging
- Addition of diagrams that correspond with the directions for use
- Revision to marketing statement to make non-essential text optional

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

IBOL	7510 P	7510P					
NAME	E. Berg	Henson					
DATE	8/9/07	8/9/07					

✓

LEWIS & HARRISON

Consultants in Government Affairs

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

telephone 202.393.3903
fax 202.393.3906

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July 20, 2007

HAND DELIVERED

Document Processing Desk [NOTIF]
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Emily Mitchell
Product Manager (32)

SUBJECT: Lonza, Inc.
Dantochlor TBS-5 (EPA Reg. No. 6836-288)
Notification of Minor Label Changes per PR Notice 98-10

Dear Ms. Mitchell:

As agent for Lonza, Inc., we are submitting a "Notification" pursuant to PR Notice 98-10 for the product **Dantochlor TBS-5 (EPA Reg. No. 6836-288)**. The purpose of this notification is the following:

- 1) Add the optional marketing language listed below. Please note this language is a reiteration of previously approved marketing language.
 - "Concentrated to clean up to 4 months and sanitize up to 2 months"
 - "(Powerful) Blue detergents (clean and deodorize)"
 - "(Helps) clean(s) (and deodorize(s)) with (powerful) blue detergents"
 - "Bleaches away stains"
- 2) Add optional language to indicate total weight and for different size packaging: "Total weight: 100 grams containing 35 gram Bleach tablet," "Bonus Pack," "3-Pack," "4-Pack," "Each tablet (2-tablet) (set) (Dual Action System) (Dual System) (System) (is concentrated to) clean up to 4 months (and sanitize for up to 2 months)," "Value Pack," "X-Pack," "X-Packs for the price of X packs," "(Concentrated) 2-tablet system," "(Concentrated) Dual System," "(Concentrated) Dual-Action System," and "(Concentrated) 2-tablet set."
- 3) Add diagrams that correspond with the directions for use.
- 4) Revise the marketing statement "Clean and Deodorize (With Every Flush)" by having the option to remove "With Every Flush."

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

- A) Application for Pesticide Notification Form, which includes a signed statement certifying compliance with PR Notice 98-10;
- B) One (1) copy of the proposed label with changes highlighted; and,
- C) Two (2) copies of the proposed labeling.

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.

Sincerely,



Georgia Anastasiou
Agent for,
Lonza, Inc.

cc: Robert Sloan (LONZA, Inc.)

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Please read instructions on reverse before completing form.

Form Application, OMB No. 2070-0060, Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other:

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 6836-288	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Dantochlor TBS-5	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) Lonza, Inc. 90 Boroline Rd. Allendale, NJ 07401 <u>PLEASE SEND ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <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.)
Notification to add optional marketing and packaging language and to add diagrams.
Please reference cover letter for details.

Notification of MINOR LABELCHANGES in Accordance With PR Notice 98-10

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 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.

Signature:

Date: **7/20/07**

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*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 <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product				<input type="checkbox"/> Other _____	
				<input type="checkbox"/> Lithograph	
				<input type="checkbox"/> Paper glued	
				<input 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 Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 740, Washington, DC 20001	Title 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.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Lonza, Inc.	
4. Typed Name Georgia Anastasiou	5. Date July 20, 2007	

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DANTOCHLOR TBS-5

(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 (Eliminates) (99% of) bacteria for 2 months
 Kills (Eliminates) (99% of) E. coli
 Kills (Eliminates) (99% of) Staphylococcus aureus (staph)
 Kills (Eliminates) (99% of) Salmonella choleraesuis (salmonella)
 Kills (Eliminates) (99% of) Enterococcus faecalis (strep)
 Kills (Eliminates) (99% of) Pseudomonas aeruginosa (pseudomonas)
 Kills (Eliminates) (99% of) Candida albicans (candida)
 Kills (Eliminates) (99% of) common household bacteria
 Kills (Eliminates) (99% of) bathroom bacteria
 Kills (Eliminates) (99% of) many odor-causing 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

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

EPA Reg. No. 6836-288
 EPA Est. No. 6836-PA-01
 Net Weight: 35 grams (1.25 oz) (each)
 (Total weight: 100 grams containing 35 gram Bleach tablet)

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

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**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.

When used as directed, Dantochlor TBS-5 will sanitize toilet bowl water, keeping it clean, clear and free of odor. Dantochlor TBS-5 gives the effectiveness of chlorine without the chlorine odor.

Dantochlor TBS-5 sanitizes toilet bowl water by (killing) (eliminating) (99% of) bacteria within 15 minutes after each flush. (Kills) (Eliminates) (99% of) bacteria within 15 minutes after each flush. Each (chlorine) tablet sanitizes the toilet bowl water (within 15 minutes) for up to 2 months

SINGLE OR TWIN-PACK BLEACH TABLET ONLY

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 (one) (white) plastic pouch away from face. Cut (one) (end) (side) pouch open with scissors (below the crimped edge) (See diagram A). **(DO NOT TOUCH TABLET).**
3. Flush toilet. Before tank refills, (hold (plastic) pouch over tank and) place one Dantochlor TBS-5 tablet (from open pouch) into the right rear corner of the tank. (See diagram B). Discard (packaging) and wash hands thoroughly.
4. No removal necessary. Product should only be used in a toilet that is flushed regularly (at least once a week).

WITH BLUE TABLETS (SINGLE OR MULTI-PACKS) ONLY

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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.
3. Hold (one) (white) (plastic) pouch away from face. Cut (one) (crimped) edge (end) (side) (of pouch) open with scissors. Hold (one) (clear) (plastic) pouch away from face. Cut (one) crimped edge (end) (side) (of pouch) open with scissors. (See diagram A). **(DO NOT TOUCH CHLORINE (BLEACH) OR BLUE (DETERGENT) TABLET).**
4. Flush toilet. Before tank refills, place one blue and one bleach tablet (place the white chlorine (bleach) and blue (detergent) tablets) (from open pouches) into the right rear corner of the tank. (See diagram B). Discard packaging and wash hands thoroughly.
5. No removal necessary. Simply replace Dantochlor TBS-5 Blue plus Bleach tablets when tablets have completely dissolved in the tank. Product should only be used in a toilet that is flushed regularly (at least once a week).

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. Discard empty container in trash.

Questions? Comments? Call *(insert telephone number here)*

(For health and safety information concerning this product 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.

(OPTIONAL MARKETING LANGUAGE):

- *Antibacterial*
- *Anti-Bacterial*
- *Antibacterial Toilet Bowl Cleaner*
- *Anti-Bacterial Toilet Bowl Cleaner*
- *Anti-Bacterial Bleach (formula)*
- *Bleach automatic toilet bowl cleaner*
- *CHLORINE CLEAR with Bleach*
- *With bleach*
- *Bleaches (stains away)*
- *Real Bleach (formula)*
- *100% bleach (formula) (tablet)*
- *(With) the (concentrated) Power of (chlorine) Bleach*
- *Bleach Cleaning (power)*
- *Bleach in every flush*
- *(A) Bleach rinse in every flush (!)*
- *Sanitizing Formula Cleans & Deodorizes (bowl)(water)*
- *Cleans & Deodorizes (bowl)(water) With (the power of) (chlorine) Bleach*
- *Deodorizes (with Bleach)*

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- Deodorizing
- Deodorizes
- Continuous deodorization
- Keeps Water Crystal Clear
- Easy To Use - Just Drop In Tank
- Easy to Use – No Mess
- Easy to Use
- Kills 99.9% of bacteria for 2 months (!) In Toilet Bowl Water After Each Flush
- Kills 99% of bacteria
- Kills (99.9% of) bacteria flush after flush
- Kills bacteria
- Kills 99.9% of bacteria (for 2 months)
- Not Harmful to Plumbing or Septic Systems (when used as directed)
- Leaves bowl sanitary
- Makes cleaning easy
- Toilet Bowl Cleaner
- Automatic Toilet Bowl Cleaner
- Controls odor-causing bacteria in the bowl water
- Controls the growth of bacteria that cause odors
- Controls odors caused by odor-causing bacteria
- Controls odor-causing bacteria
- Controls the growth of bacteria
- Controls bacterial growth
- 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 (for up to 4 months)
- Continuous sanitizing action
- Continuous cleaning and sanitizing action
- No Mess in tank
- No-Mess formula
- No Mess formula
- Makes cleaning easier
- Instant, continuous bowl cleaning (with every flush)
- Bleach cleaning
- Bleach
- Bleaches
- Bleaches bowl (with)
- Bleach toilet (bowl) cleaner
- (With) the (concentrated) power of bleach(!)
- For colored toilets
- For use with many other blue drop-in(s) (tablets)
- Actual size (tablet) (system)
- Bonus Size (tablet) (system)
- 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 2 months
- Cleans (and sanitizes) with every flush (for up to 2 months)

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- Sanitizes up to 2 months
- Cleans and sanitizes up to 2 months
- Sanitize
- Sanitizes
- Sanitizing
- Sanitizes with Bleach
- Sanitizing Formula
- Sanitizing Formula Cleans (bowl)
- Sanitizing Formula Cleans and Deodorizes (bowl) (water)
- Sanitizing Formula Kills (99.9% of) bacteria for 2 months (in toilet bowl water) (after each flush)
- (Each) (Tablet) sanitizes up to 2 months
- Sanitizes with every (each) flush
- Sanitizes for up to 2 months; cleans for 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
- (Is) concentrated to clean up to 4 months
- Concentrated (formula) (tablet) to sanitize (Kill 99.9% of bacteria) (and clean) for up to 2 months
- Cleans
- Cleaner
- Cleans with bleach
- Cleans away stains
- Cleans away odors
- Makes bowl cleaner
- Makes cleaning easy (easier)
- Cleans for up to 4 months
- Cleans for up to 4 months and sanitizes for 2 months
- Cleans (away) tough stains
- 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-5 directly into the bowl for (continuous) (up to 2 months) of sanitization and cleaning
- Each system cleans up to 4 months
- Each (set) pair (of tablets) (are) concentrated to clean up to 4 months (and kill 99.9% of bacteria for (up to) 2 months
- Each (set) pair (of tablets) (are) concentrated to clean up to 4 months and sanitize for (up to) 2 months
- (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(!)
- Freshens
- Freshening
- Continuously freshens (with every flush)
- Freshens bowl (and bathroom)
- Freshens bowl
- Freshens with every flush
- Refreshes
- Refreshes bowl with every flush
- Drop-in
- (Contains) No phosphates or phosphorous compounds
- Time release formula (formulation)

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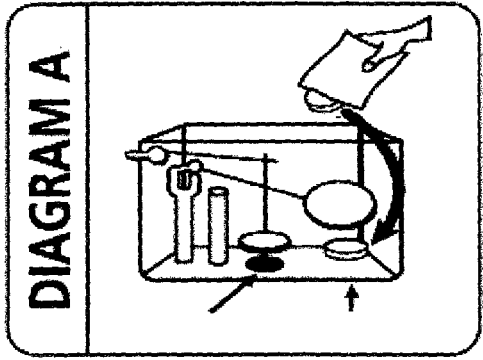
- Formulated to deliver consistent (powerful) cleaning and sanitization for up to 2 months!
- For 4-month duration simply add a new, Dantochlor TBS-5 bleach tablet when the first tablet has completely dissolved in the tank.
- (Has) powerful blue detergent(s) plus chlorine to bleach away stains
- Combined power of bleach and (blue) detergents
- Concentrated size
- Concentrated tablet
- Concentrated to clean up to 4 months and sanitize up to 2 months.
- (Powerful) Blue detergents (clean and deodorize)
- (Helps) clean(s) (and deodorize(s))with (powerful) blue detergents
- Bleaches away stains

[Note to reviewer: The following phrases are for packages that contain two or more tablets:]

- 2-Pack (set)
- 2 months of sanitization and cleaning (power)!
- Each tablet kills 99% of bacteria for up to 2 months (for a total of 4 months)
- Twin Pack
- Bonus Pack
- 3-Pack
- 4-Pack
- Each tablet (2-tablet) (set) (Dual Action System) (Dual System) (System) (is concentrated to) clean up to 4 months (and sanitize for up to 2 months).
- Value Pack
- X-Pack
- X-Packs for the price of X packs

- (Concentrated) 2-tablet system
- (Concentrated) Dual System
- (Concentrated) Dual-Action System
- (Concentrated) 2-tablet set

Bleach



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Blue + Bleach

