

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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

SEP -2 2010

Subject: Dantobrom TBS-6

EPA Reg. No. 6836-300

Application Dated: August 3, 2010 Receipt Date: August 5, 2010

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 with a comment.

Proposed Notification:

- Revise 'Salmonella choleraesuis' to new name 'Salmonella enterica'
- Add optional barcode, 'country of origin' statement, and 'manufactured in' statement
- Add optional marketing language
- Add missing diagram referenced in Directions for Use
- Update Storage and Disposal per PR Notice 2007-4

Comment:

Based on a review of the material submitted, the following comment applies:

Add the statements "Nonrefillable container. Do not reuse or refill this container." preceding the statement "Discard empty container...".

General Comment:

This application for notification to revise the product 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 Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

Acting Product Manager (32)

Regulatory Management Branch II

Antimicrobials Division (7510P)

| Please read instructions on rever | se before completing for | n Approved, OMB 1 | No. 2070-0060, Approval e | хрјг 15-31-98 | | | | | | |
|---|--------------------------------------|--|---|---|---|--|--|--|--|--|
| | United States | | Registrati | | OPP Identifier Number | | | | | |
| EPA | Environmental Protection | 1 Agency | Amendme | | | | | | | |
| , | Washington, DC 2046 | 0 , | _ | ziit | | | | | | |
| | | | | | | | | | | |
| Application for Pesticide - Section 1 | | | | | | | | | | |
| 1. Company/Product Number | Γ | 1 | roduct Manager | | 3. Proposed Classification | | | | | |
| 6836-300 | | | a Henson | | | | | | | |
| 4. Company/Product (Name) | | 1 | PM# 32 | | None Restricted | | | | | |
| Dantochlor TBS-6 5. Name and Address of Applicant (Include ZIP Code) | | | ited Review. In accordance | on 3(c)(3)(b)(I) my product is similar | | | | | | |
| Lonza Inc. | ant (2770111100 2212 00000) | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: | | | | | | | |
| 90 Boroline Roa | d | | | | | | | | | |
| Allendale, NJ 07 | 401 | I | EPA Reg. No. | | | | | | | |
| | | Produc | Product Name | | | | | | | |
| Check if this is a new add | lress | | | | | | | | | |
| Section – II | | | | | | | | | | |
| Amendment - Explain t | pelow. | | Final printed labe | ls in response to Age | ncy letter dated | | | | | |
| Resubmission in respor | se to Agency letter dated | | "Me Too" Application | | | | | | | |
| Notification - Explain t | elow. | | Other - Explain be | elow | | | | | | |
| Explanation: Use add | itional page(s) if necessary. | (For Section I a | nd Section II.) | | | | | | | |
| _ | - · · | *Not Subje | ct to PRIA* | | | | | | | |
| Label Notification to up | odate Storage and Disposal l | | | | | | | | | |
| | | | LETTER FOR D | DETAILS. | | | | | | |
| This notification is consist | tent with the provisions of P | R-Notice 98-10 | and EPA regulations | at 40 CFR 152.4 | 6, and no other changes have | | | | | |
| | or the confidential statemen | | | | | | | | | |
| | y false statement to EPA. I f | | | | | | | | | |
| | 152.46, this product may be | e in violation of | FIFRA and I may be | subject to enforce | ement action and penalties | | | | | |
| under sections 12 and 14 | of FIFRA. | | | | | | | | | |
| Signature: Date: 8-3-10 | | | | | | | | | | |
| Section – III | | | | | | | | | | |
| Material This Product Wi | II Be Packaged In: | | | | | | | | | |
| Child-Resistant Packaging | Unit Packaging | | Water Soluble Packag | ging | 2. Type of Container | | | | | |
| Yes* | Yes | | Yes | | Metal | | | | | |
| No · | ⊠ No | | ⊠ No | | Plastic | | | | | |
| *Certification must be | If "Yes" | No. per | If "Yes" | No. per | Glass | | | | | |
| submitted | Unit Packaging wg | t. container | Package wgt. | container | Paper | | | | | |
| | | | | | Other (Specify) packets | | | | | |
| 3. Location of Net Contents | Information 4 Size(s |) Retail Container | | 5. Location of I | abel Directions | | | | | |
| Label [| ✓ Container ✓ Container | | | On Label | | | | | | |
| | 1 oz. to | | | On labeling | g accompanying product | | | | | |
| 6. Manner in Which Label i | | Lithograph | Other | | , | | | | | |
| | Ľ ∇ | Paper glued Stenciled | | | | | | | | |
| | | | | | | | | | | |
| | | | on – IV | | | | | | | |
| | tems directly below for identificati | | be contacted, if necessary, | to process this appli | | | | | | |
| Name Joanna Holcombe | | Title | orgial Dogulatory Sc | rrioos | Telephone No. (linglude Area Code) 201-316-929? | | | | | |
| Joanna Holcombe Sr. Commercial Regulatory Services 201-316-9297 Associate | | | | | | | | | | |
| Certification Certification Received | | | | | | | | | | |
| | Certi | fication | | I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge | | | | | | |
| | have made on this form and all att | achments thereto are | | | | | | | | |
| that any knowingly false or i | have made on this form and all att | achments thereto are nable by fine or imp | | | | | | | | |
| | have made on this form and all att | achments thereto are nable by fine or important | risonment or both under ap | oplicable law. | | | | | | |
| that any knowingly false or i | have made on this form and all att | achments thereto are nable by fine or important | | oplicable law. | | | | | | |
| that any knowingly false or i | have made on this form and all att | achments thereto are nable by fine or important and are seen as a seen are nable by fine or important and are seen are nable by fine or important are nable | risonment or both under ap | oplicable law. | | | | | | |

4

Via FedEx

Ms. Wanda Henson, 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 Life Science Ingredients Commercial Regulatory Services

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

Joanna Holcombe August 3, 2010

SUBJECT: Dantochlor TBS-6, EPA Reg. No. 6836-300
Application for Label Notification

Dear Ms Henson:

I am submitting an application to accomplish the following for the above named product:

- Revise Salmonella choleraesuis to its new name Salmonella enterica;
- Add optional barcode, "country of origin" statement, and "manufactured in" statement;
- · Add optional marketing language;
- · Add missing diagram referenced in the Directions for Use; and
- Update the Storage and Disposal language per PR Notice 2007-4.

Please find the enclosed documents in support of this notification:

- Application for Notification;
- One copy of the proposed label with changes highlighted; and
- Two copies of the proposed label.

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



DANTOBROM 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

(Each tablet) Kills (Eliminates) (99% of) bacteria for (2 months) (8 weeks)

Helps Keep Your Toilet Bowl Fresh and Clean Recommended for frequently flushed toilets Sanitizes and cleans for 8 weeks Kills (germs)(bacteria) for 8 weeks

Kills E. coli

Kills Staphylococcus aureus (staph)

Kills Salmonella enterica (salmonella)

Kills Enterococcus faecalis (strep)

Kills common household (germs)(bacteria)

Kills bathroom (germs)(bacteria)

Kills many odor-causing (germs)(bacteria)

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% |
| Inert Ingredients: | 2.0% |
| TOTAL: | |

Available bromine:

39.2%

Available chlorine:

44.2%

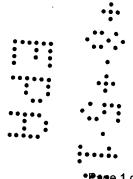
KEEP OUT OF REACH OF CHILDREN **DANGER**

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

EPA Reg. No. 6836-300 EPA Est. No. 6836-PA-01 Net Weight 35 grams

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

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



Dantobrom TBS-6 [] and ()= Denotes alternative / interchangeable language EPA Reg. No. 6836-300 EPA Stamped label 11-8-01, Draft 8-2-10

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

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.

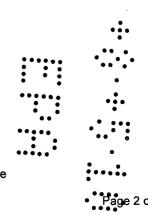
IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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.

PHYSICAL AND CHEMICAL HAZARDS

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

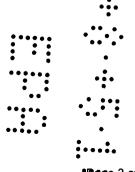


(OPTIONAL MARKETING LANGUAGE):

- Antibacterial
- 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 8 weeks! 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

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

- 2-Pack
- 2 months (4 weeks) of sanitization and cleaning
- Each tablet kills 99% of bacteria for up to 2 months (for a total of 2 months)
- Twin Pack
- Bonus Pack
- 3-Pack
- 4-Pack



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

Dantobrom TBS-6 sanitizes toilet bowl water by killing 99.9% of (germs)(bacteria) in 1 minute after each flush. Each tablet sanitizes for 8 weeks. Eliminates 99.9% of (germs)(bacteria) in 1 minute after each flush.

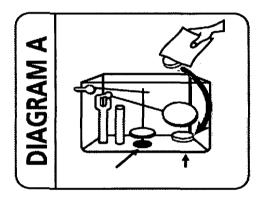
Remove tank cover and cut open package.

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 Dantobrom TBS-6 tablet into the right rear corner of the tank. (See diagram A) Discard plastic pouch and wash hands thoroughly.
- 4. No removal necessary. Each tablet sanitizes for 8 weeks. When tablet has dissolved, replace with a new tablet. Product must be used in a toilet that is flushed regularly.

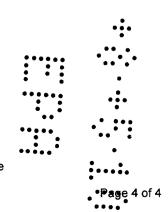


STORAGE AND DISPOSAL

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 or offer for recycling if available.

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.



Dantobrom TBS-6 [] and ()= Denotes alternative / interchangeable language EPA Reg. No. 6836-300 EPA Stamped label 11-8-01, Draft 8-2-10