

PM 32

6836-275

8-30-99

1 of 4



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

6836-275

Date of Issuance:

AUG 30 1999

Term of Issuance: Conditional

Name of Pesticide Product: Dantobrom

TBS-5C

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Wendy A. McCombie, Agent for Lonza, Inc
c/o Lewis & Harrison
122 C Street N.W., Suite 740
Washington, D.C. 20001

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to the use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit two copies of the revised final printed label for the record changing the EPA File symbol 6836-ETL to EPA Registration Number 6836-275.
3. Make every effort to assure that all customers who use this product understand that a disinfectant product is also required and that they are aware of the labeling restrictions contained on the label and technical bulletin(s).
4. You must make the following changes to your proposed product label before these products can be registered:

You must remove the claim "one tablet sanitizes for 13 weeks". You may submit efficacy data to support this claim with a label amendment application.

Signature of Approving Official:

Thomas D. Lemmle
for Robert S. Brennis
Product Manager 32

Date:

AUG 30 1999

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4. (Continued)

The use of the phrase "kills 99.9% of all germs" is unacceptable. Claims for such killing action imply a disinfectant level of activity, thus suggesting a higher level of activity than what we accept for an in-tank sanitizer. Delete this statement.

On the upper right panel of the label, change "...by killing 99.9% of all germs" to read "by reducing the number of bacteria by 99.9% within one minute after each flush...". On the same panel, delete the term "eliminates" and replace with "reduces." On the same panel, change "...kills Escherichia coli (E. Coli).." to read "reduces Escherichia coli (E. Coli).."

Efficacy for these products is primarily against bacteria. The use of the term germ(s) in the claims makes the inference of efficacy against a broader spectrum of pathogenic microorganisms (bacteria, fungi and viruses). **In all instances the term "germ(s) should be replaced with the term "bacteria (and fungi)" on the Dantobrom TBS-5C label.**

On the center panel revise "Kills 99.9% Of Germs.." to read "Reduces 99.9% Of The Number of Bacteria (and Fungi)".

Delete the claim "Long Lasting!" As stated in Federal Register Notice Volume 49 Number 188 page 37959, terms implying that protection will extend for an indefinite period of time of the products performance are not acceptable.

Delete the phrase "ideal for frequently flushed toilets." The word "ideal" is considered unacceptable label language.

Revise "Kills germs for over 3 months" to read "Reduces the number of bacteria for 3 months."

Change the claim "Kills" E. Coli, Staphylococcus aureus, Salmonella choleraesuis, Stretococcus faecalis, common household and odor-causing to "Reduces" E. Coli, Staphylococcus aureus, Salmonella choleraesuis, Streptococcus faceless, common household.

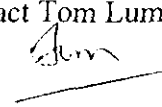
Revise "Kills odor-causing germs" to read "Controls the growth of odor-causing bacteria".

5. Under Storage and Disposal add "Do not contaminate water, food, or feed by storage or disposal".
6. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. A copy of our product chemistry evaluation and efficacy evaluation of a similar product are enclosed.

If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.



DANTOBROM TBS-5C

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:

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

In-Tank Sanitizer
In-Tank Automatic Toilet Bowl Cleaner
Sanitizes Toilet Bowl Water After Each Flush
Kills 99.9% Of Germs In Toilet Bowl Water After Each Flush
Cleans and Deodorizes With Every Flush
Helps Keep Your Toilet Bowl Fresh and Clean
— Long Lasting! —

Ideal for frequently flushed toilets
Sanitizes and cleans for over 3 months
Kills germs for over 3 months
Kills E. coli X
Kills Staphylococcus aureus (staph)
Kills Salmonella choleraesuis (salmonella)
Kills Streptococcus faecalis (strep)
Kills common household germs
Kills odor-causing germs x

Change Kills to 'Reduces'

"Reducing"

"Reduces et al."

When used as directed, Dantobrom TBS-5C will sanitize toilet bowl water, keeping it clean, clear and free of odor. Dantobrom TBS-5C gives the effectiveness of chlorine without the chlorine odor. **Dantobrom TBS-5C sanitizes toilet bowl water by killing 99.9% of germs within one minute after each flush. Each tablet sanitizes for 13 weeks. Eliminates 99.9% of germs within one minute after each flush.** Kills Escherichia coli (E. coli), Streptococcus faecalis (strep), Salmonella choleraesuis (salmonella), and Staphylococcus aureus (staph).

Tablets should be used in toilets that are flushed (daily) (regularly).

For best results, clean toilet thoroughly first, including under the rim with a toilet bowl cleaner. Do not touch tablet directly. 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:

Flush toilet. When water level in tank is low, drop tablet into [tank near sidewall closest to float and away from water valve opening] [right rear corner of the tank]. When tablet has dissolved, replace with a new tablet. Each tablet sanitizes for 13 weeks.

STORAGE AND DISPOSAL:

Store in original container in areas inaccessible to small children in a cool, dry, well-ventilated area. Do not store at elevated temperatures. Discard empty container in trash. Add "Do NOT contaminate water, food, or feed by storage or disposal." 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.

* One tablet sanitizes for 13 weeks]

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:	100%

Revise All "germs" to "bacteria"

Available bromine 39.2%
Available chlorine 44.2%

KEEP OUT OF REACH OF CHILDREN
DANGER

See Side/Back Panel For
Additional Precautionary Statements

EPA Reg. No. 6836- ETL
EPA Est. No. 6836-PA-01
Net Weight 100 gm.

Manufactured by:
LONZA Inc., 17-17 Route 208, Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 30 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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body

Kills 99.9% of E. coli in one minute
Kills 99.9% of Staphylococcus aureus (staph) in one minute
Kills 99.9% of Salmonella choleraesuis (salmonella) in one minute
Kills 99.9% of Streptococcus faecalis (strep) in one minute
Kills 99.9% of common household germs in one minute
Kills 99.9% of odor-causing germs in one minute
Kills 99.9% of germs in one minute

~~Kills 99.9% of germs for over 3 months~~
Now sanitizes and cleans for over 3 months
Sanitizes 75% longer than Dantobrom TBS
Makes weekly cleaning easier
Bleaching action
Whitening and brightening action
Does the cleaning for you
Drop in the tank and walk away
No scrubbing
Daily toilet cleaning and maintenance
Dye free
Leaves no visible residue
Continuous anti-bacterial action
Continuously kills 99.9% of germs

Each tablet kills 99.9% of:
Escherichia coli
Staphylococcus aureus (staph)
Salmonella choleraesuis (salmonella)
Streptococcus faecalis (strep)
*Pseudomonas aeruginosa (pseudomonas)
*Candida albicans

*Based on a 15-minute contact time

All instances
of "Kills" must
be changed to
"Reduces." All instances
of "germs" must be changed
to "bacteria (and fungi)" - optional

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