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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

July 14, 1999

**MEMORANDUM**

**Subject:** Efficacy Review and Label Review for "Dantobrom TBS-5B", for " Dantobrom TBS-4A", and for " Dantobrom TBS-5A" EPA Reg. No(s) 6836-ETU, 6836-ETE, and 6836-ETG  
Case Nos. 065852, 065850 and 065851  
DP Barcodes: D255593, D256803 and D256805

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**Applicant:** Lonza, Inc.,  
17-17 Route 208  
Fair Lawn, NJ 07410

**Formulation From Label**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
1-bromo-3-chloro-5, 5 dimethylhydantoin .....	60.00
1,3-dichloro-5, 5-dimethylhydantoin .....	27.40
1,3-dichloro-5-ethyl-5-methylhydantoin .....	10.60
<u>Inert Ingredient (s)</u> .....	<u>2.00</u>
Total .....	100.00

*PC 006315*

## BACKGROUND:

The subject products "Dantobrom TBS-4A" (EPA Reg. No. 6836-ETE), "Dantobrom TBS-5A" (EPA Reg. No. 6836-ETG), and "Dantobrom TBS-5B" (EPA Reg. No. 6836-ETU) are new applications for three end-use products which consists of identical formulations. All three products are being proposed for use as a toilet bowl in-tank sanitizers. All three proposed end-use products are reported to be identical in composition to two other Lonza registered products, "Dantobrom" (EPA Reg. No. 6836-117) and "Dantobrom TBS" (EPA Reg. No. 6836-255).

The current submissions are new applications which contain in-tank sanitizing data and three proposed labels (MRID #448019-04 & -05). All data reports and labeling are summarized below.

## RECOMMENDATIONS:

The submitted microbiological efficacy developed by the In-Tank Sanitization Test Method satisfactorily demonstrates reducing the test microorganisms *Enterococcus faecalis*, *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Escherichia coli* at least 99.9% over the "0" time control and over the parallel untreated inoculated control at contact times of 1 minute, 15 minutes, and 30 minutes when exposed to a minimum active halogen level of 0.60 ppm of total halogen (as Cl<sub>2</sub>). The submitted microbiological data showed that in toilets which were standardized to reflect 6 liters +/-0.2 liters of water per flush with 12 flushes daily a 90 gram tablet (cold water 10-15°C) (warm water 25-30°C) lasted for an average 2,243 hours or 13.40 weeks.

For *Candida albicans*, over 2.50 ppm of halogen is required to show 99.9% reduction at a 1 minute contact time. A minimum level of 0.52 ppm of active halogen is needed to show 99.9% reduction at 15 minutes and at 30 minutes contact time with the overall average with water (hot and cold) of 2,286 hours and/or 13.60 weeks .

Based on the submitted microbiological efficacy data, product effectiveness as an in-tank sanitizer was demonstrated and the submitted data reports are considered satisfactory.

**Labeling Comments: These comments are applicable for the proposed labels of all three Dantobrom TBS products unless otherwise stated.**

The use of the phrase "kills 99.9% of germs" is unacceptable. Claims for such killing action imply a disinfectant level of activity thus suggesting a higher level of activity than that which is proposed for the product, an in-tank sanitizer.

On the upper right panel of the labels, 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 right 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)..."

Additionally, 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" on the Dantobrom TSB-5B label, and on the TSB-4A and TSB-5A labels "germ(s)" should be replaced with "bacteria and fungi."

**The following comments all refer to claims present in the center panel:**

Item #4, revise "kills 99.9% of germs..." to read "Reduces 99.9% of a number of bacteria in toilet bowl water after each flush."

Item #7, which makes the claim of "long lasting", must be deleted. As per FR Notice, Vol. 49, #188, page 37959, 09-26-84, terms implying that protection will extend for an indefinite period of time are considered unacceptable and unwarranted. Also, Items #9 and #10 already specify the time frame of the products' performance.

Item #8, delete the phrase "ideal for frequently flushed toilets." The wording "ideal" is considered unacceptable label language. This superlative is also described and found in the same FR Notice indicated above in item #2.

Item #9, revised to read "sanitizes and cleans for 3 months."

Item #10, revise "kills germs for over 3 months" to read "reduces the number of bacteria for 3 months."

Item #11, change "kills E. coli" to read "Reduces E. coli."

Items #12 through #18, change the word "kills" to read "reduces."

Item #18, revise "kills odor-causing germs" to read "controls the growth of odor causing bacteria."