5813-76

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 1 6 2003

Eric Tamichi Clorox Services Company P.O. Box 493 Pleasanton, CA. 94566-0803

SUBJECT: March 19, 2003 Amendment Application Clorox MTOC EPA Registration 5813-76

Dear Mr. Tamichi:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment(s) listed below.

1. The proposed use as a disinfectant with fungicidal activity against *Candida albicans* in the presence on hard, non-porous surfaces for a contact time of 10 minutes is not acceptable.

2. The proposed use as a sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* are acceptable.

3. A number of proposed label claims regarding the use of the product as a sanitizer [page 4 of the proposed label] could be misleading and must be changed accordingly.

- "Has the power of Clorox [bleach] to kill 99.9% of [household germs -or- bacteria]", delete the word "power", and replace with "effectiveness".

- "Kills [more than] 99.9% of [household] bacteria -or- germs", delete the wording "more than".

- "kills 99.9% of household germs -or- bacteria with the power of clorox {bleach}, delete the wording "power" and replace with "effectiveness".

4. The proposed label claims that the product "kills ... germs ... in toilet bowl water." These claims should be revised to read "kills ... germs ... on hard nonporous toilet bowl surfaces." Toilet bowl water was not demonstrated by efficacy testing.

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5. The claim for Rotavirus should be listed on page #3 of the proposed label under disinfecting claims only for 10 minutes. Also, the listing of Rotavirus under sanitization is not acceptable. On page #4, the bottom lower left panel under the sanitization claims, delete the label claim for "Rotavirus". On the right middle panel of page #4, the claim for sanitization of toilet bowl water in 5 minutes is not acceptable.

6. The use directions for under disinfection should be expanded to indicate that the product is to used be undiluted.and that the usage is only for non-medical areas (i.e., homes, schools, etc.). You must revise label so that the label lists the major non-medical environments for usage (i.e., homes, schools) where toilet bowls can be disinfected with the product.

7. Since the data submitted *Candida albicans* were not acceptable, the claim for *Candida albicans* must be deleted from the left panel of page #3 label.

8. On page #4 of the proposed label, delete the wording "power", delete the virus "Rotavirus" on the left lower panel.

9. On the middle right panel on page #4, delete the phrase "germs in toilet bowl water.

10. On the middle left panel on page #4. delete the phrase "or germs or pathogens (in toilet and/or bowl water).

11. On lower left panel on page #4, delete "germs -or- bacteria-or- microorganisms in (toilet bowl water).

12. On the top of page #4, revise "To sanitize (toilet bowl)" to read "To sanitize (toilet bowl surfaces).

13. On the bottom left panel of page #2, the use of the term "new" is only acceptable for six(6) months. After six months and at the next label printing, delete the term "new".

See enclosed review for additional information regarding the performance data. A copy of your stamped conditionally acceptable label is enclosed. Please submit a revised finished label for our files. If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,

Robert S. Brennis Product Manager (32) Regulatory Management Branch II Antimicrobial Division (7510-C) r

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Note: Bold, italicized text is information for the reader and is not part of the label, (Bracketed Information is optional text.) Text separated by a diamond builet (◆) denotes -and/or options. <u>Underlined text is new</u>. Strike-through (www) means removed. The terms 'uninal or uninals' can be substituted or added where the terms 'toilet or tollets' appear. EPA Reg. No. 5813-76 Clorox MTOC Page 1 of 5

CLOROX®

ACCEPTED WITH COMMENTS IN EPA Letter Dated SEP 16 2003

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KEEP OUT OF REACH OF CHILDREN DANGER: CORROSIVE

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.

IN EITHER CASE, CALL A POISON CONTROL CENTER OR DOCTOR FOR TREATMENT ADVICE.

NET Contents: 24 fl oz

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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 Clean [1 [1] Flush toilet before cleaning. [2] Apply product under and around [3] Scrub entire bowl with a stiff bru [4] Do not allow pets or children to [5] Flush toilet. (Note that prolonged contact with m	ush and allow to sit for 5 minutes.
 Cleaning Claims: For cleaner fresher tollet -or- bathroom Will not scratch surfaces Leaves bathroom -and/or- tollet [bowl] fresh and clean Freshens tollet bowl -or- bathroom Easy to use [for cleaning] Bleach in the bowl! Makes your [cleaning] job easier Has the [cleaning] power of bleach MTOC with bleach in a gel formula -or- In a unique bleach gel formula -or- Rain Clean -or- Fresh Scent -or- With power of Clorox® Bleach in a gel formula -or- gel formula -or- With the power of Clorox® Bleach in a convenient gel formula Contains sodium hypochlorite plus a cleaner Non-abrasive formula for cleaning -or- which will not scratch surfaces For [cleaning] use on both white and colored hard surfaces Thick Clorox® Bleach toilet bowl cleaner Contains the power of Clorox® Bleach in a gel formula in -or- around the bowi Brightens and removes dirt stains Brightens with the power of Clorox® bleach Whitens with the power of Clorox® bleach 	 Leaves [the] [your] [toilet] bowl bleach-clean! Leaves the bowl bleach-fresh Keeps [the] (your] toilet (bowl) bleach-clean Heips keep [the] (your] toilet (bowl) fresh and clean Heips keep [the] (your] toilet (bowl) clean, clear, and free of odor Cleans -and/or- deodorizes Cleans -and/or- deodorizes with the power of [Clorox®] bleach The only manual toilet bowl cleaner with the power of Clorox® [bleach] Clorox® [bleach] cleaning power Effectiveness -or- Power of [Clorox®] bleach Contains a powerful cleaner plus [Clorox®] bleach Contains cleaners plus powerful Clorox® Bleach Leaves toilet surfaces [clean and] sanitary An effective cleaner for use in the toilet -or- on toilet surfaces Better cleaning power -of bleach For a cleaner, fresher toilet Manual -or- Bleach toilet bowl cleaner Remeves stains and leaves bowl sanitary
GENER 	AL CLAIMS • Great for toilets • Clings to sides of bowl better

- [New][and][Improved] Formula
- Pleasant fragrance
- · Has a clean fresh scent -or- fragrance
- + Concentrate -or- Concentrated formula
- · Contains no abrasives -or- acids
- · Won't splash or drip and will rinse away easily
- . Fully dissolves [in the bowl water] no messy residue to remove
- · Non-abrasive formula [that will not scratch surfaces]
- · Removes odors
- · Deodorizes and has a clean, fresh scent -or- fragrance
- . [New] Improved clinging action Thick formula · Cleans and deodorizes the toilet bowl [water] · Removes -or- Prevents -or- Eliminates odors Commercial Solutions
- Will not harm plumbing or septic systems
 Thick gel formula coats the bowl and discoves stains for
- deep-down cleaning Thick gel formula coats the bowl for deep-dewn cle
- With clinging action

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DISINFECTION

To Disinfect [toilet bowl]:

[1] Start with a clean bowl -or- Preclean before disinfecting.

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[2] Empty bowl water.

- [3] Apply product under and around rim to coat the inside of bowl.
- [4] Scrub entire bowl with a stiff brush and allow to sit for 5 minutes -or- 10 minutes.
- [5] Do not allow pets or children to access the toilet during this time.

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[6] Flush toilet.

(Note that prolonged contact with metal, old porcelain, or worn plastic laminate may cause discoloration. In addition, do not use with ammonia, as hazardous gases may be released \mathbf{z} . Use Clorox Undiluted in Nomes, schools, \mathbf{z} And

Disinfecting Claims:

5-Minute Contact Time:

- Kilis [common] organisms[: Staphylococcus aureus [Staph] (-and/or- Salmonella choleraesuis [Salmonella] -and/or- Retavirus [in 5 minutes]]
- A toilet product for cleaning and disinfecting [against Staphylococcus aureus [Staph] -and/or- Salmonella choleraesuis [Salmonella] -and/or-Retavirus in 5 minutes] - Acctr.
- Disinfects (and cleans) tollet (bowi) surfaces (against Staphylococcus aureus [Staph] -and/or- Salmonella choleraesuis [Salmonella] -and/or- Rotavirus in 5 minutes]

General Disinfecting Claims:

- Kills bacteria -or- germs while it cleans [and disinfects]
- Kills odor-causing bacteria[: Salmonella choleraesuis
- -and/or- Staphylococcus aureus -and/or- Escherichia coli] in the toilet bowl
- Antibacterial [formula] -or- Disinfecting [formula]
- This product kills Salmonella choleraesuis, Staphylococcus aureus, and Escherichia coli found in the toilet -or- on the toilet
- Bacteria-fighting -or- Germ-fighting formula
- Disinfects (and cleans your tollet) [against Salmonella choleraesuis, Staphylococcus aureus, and Escherichia coli]
- Tollet disinfectant [and cleaner]
- Broad spectrum disinfectant -or- disinfectancy cleaner
- · Fast acting toilet disinfectant -or- toilet cleaner
- [Effective] toilet disinfectant [in presence of [5%] soil load -ororganic soil]
- Bactericide -or- Bactericidal -or- Virucide -or- Virucidal -or-Germicide -or- Germicidal
- This cleaner disinfectant combines cleaning and disinfecting
- Disinfects under the rim
- Eliminates odors caused by bacteria -or- germs -or- Controls odors produced by [common] [toilet].germs

10-Minute Contact Time:

Kills [common] bacteria[: Staphylococcus aureus [Staph]
 -and/or- Salmonella choleraesuis [Salmonella] [in 10 minutes]
 -and/or- Escherichia coli [E. coli] -and/or- Rotavirus
 [in 10 minutes]]

other non-medical locations.

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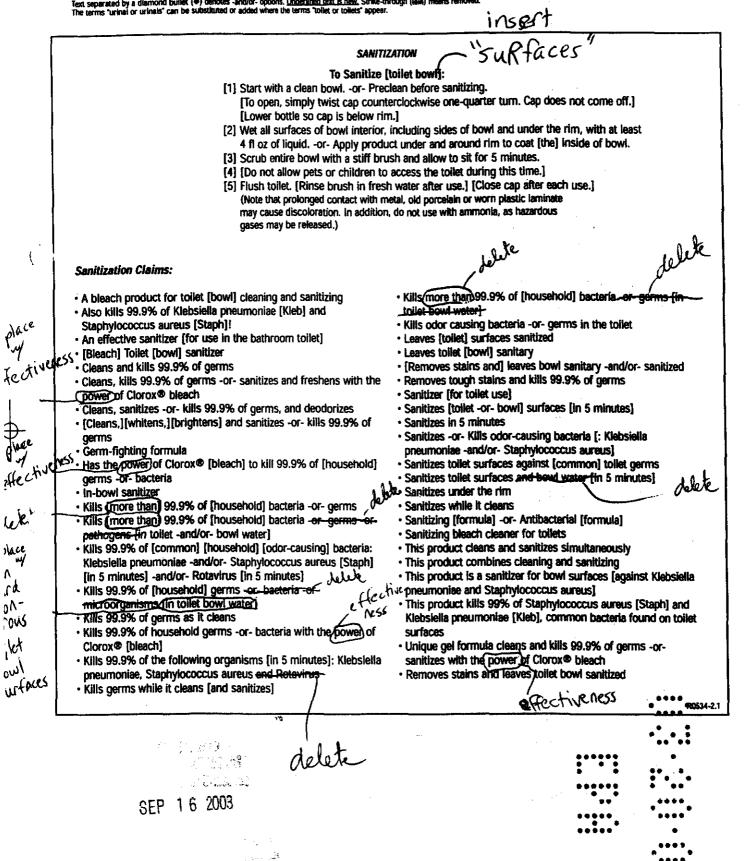
- A toilet product for cleaning and disinfecting [against Staphylococcus aureus [Staph] -and/or- Salmonella choleraesuis [Salmonella] -and/or- Escherichia coll [E. coli] -and/or- Rotavirus in 10 minutes]
- Disinfects [and cleans] toilet [bowl] surfaces [against Staphylococcus aureus [Staph] -and/or- Salmonella choleraesuis [Salmonella] -and/or- Escherichla coli [E. coli] -and/or- Bandida -albicans--and/or- Rotavirus in 10 minutes]
- Kills odor-causing bacteria
- Antibacterial (formula -or- action)
- · Germ-fighting [formula]
- Toilet disinfectant -and/or- cleaner
- Bleach toilet disinfectant [-and/or- cleaner]
- Disinfecting bleach cleaner [for toilets]
- A bleach product for toilet cleaning and disinfecting
- · Disinfects nonporous [hard][solid] surfaces of toilet bowls
- This product cleans and disinfects simultaneously
- Disinfects against -or- Kills [common] toilet bacteria -or- germs
 [: Salmonelia choieraesuis [Salmonelia] -and/or- Staphylococcus aureus [Staph] -and/or- Escherichia coli [E. coli] -and/or-Rotavirus]
- Disinfects -and/or- Deodorizes [against odor-causing bacteria -or- germs]
- Disinfects and deodorizes by killing (common) [toilet] germs and controlling their odors
- Kills the virus that causes common colds[: Rotavirus]
 Kills -and/or- Disinfects Rotavirus

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ENVIRONMENTAL CLAIMS

- Contains biodegradable cleaning agents -and/or- cleaners
 -and/or- surfactants -and/or- soaps and detergents
- The bleach in this product breaks down almost entirely to sait and water -and/or- This bottle is made of ____% post-consumer recycled [HDPE] plastic -and/or- [This product is] [S]suitable for septic [systems] -and/or- wastewater systems -or- treatment plants
- Not harmful to plumbing and septic systems -or- Safe for [plumbing and] septic systems

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

DANGER: CORROSIVE.

May cause severe irritation or damage to eyes and skin. Protect eyes when handling. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. For sensitive skin or prolonged use, wear gloves. Wash after contact with product. Use only in well-ventilated areas.

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. Do not give anything by mouth to an unconscious person. IN ALL CASES, 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. Clorox Information Line: 1-800-XXX-XXXX

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Physical and Chemical Hazards:

This product contains bleach. Do not use or mix with other household chemicals such as other toilet bowl cleaners, rust removers, acids or products containing ammonia. To do so will release hazardous, irritating gases. Avoid contact with clothes, fabric, carpet, wood, painted and paper surfaces.

Storage and Disposal: Store in a location inaccessible to children. Tightly close cap between uses. Do not reuse empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

Mfd. for & ©2001 The Clorox® Company, Oakland, CA 94612 EPA Reg. No. 5813-76 EPA Est. No. 5813-GA-01 (Actual EPA Est. No. in code below.) ACCEPTED		••••• •••• •••• ••••
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