

S813-24

07-13-2009

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



United States
Environmental Protection
Agency

Office of Pesticide Programs

JUL 13 2009

J. Evelyn Lawson
Senior Regulatory Information Scientist
The Clorox Company
c/o PS&RC; P.O. Box 493
Pleasanton, CA 94566-0803

FILE COPY

Subject: Application for Amended Registration
Product Name: Tilex
EPA Registration Number: 5813-24
Application Date: January 30, 2009
Receipt Date: February 20, 2009

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments.

Proposed Amendment

- Add three (3) organisms to label: Escherichia coli with extended beta-lactamase resistance, Escherichia coli O157:H7, and Community Acquired Methicillin-Resistant Staphylococcus aureus
- Revision of Storage and Disposal Statement
- Addition of marketing claims

Acceptable Data

The proposed label claims are acceptable regarding use of the product, Tilex (EPA Reg. No. 5813-24), as a disinfectant against the following microorganisms on hard non-porous surfaces. Directions were not provided for bactericidal claims consistent with the data. The registrant must add the appropriate use dilution.

Labeling Comments

1. The following claims must be removed from the proposed label:

- Kills 99.9% of household mold
- Kills 99.9% of household mold and mildew in just 5 minutes
- Kills most common household molds
- Attacks mildew at its roots
- Kills mold and mildew at its roots
- Seeks out and kills mildew at its roots
- Seeks out and kills mildew even in hard to clean places
- This product penetrated deep beneath the surface

2. You must clarify the claim for cement pool areas. Specifically, you must state whether the claim is for cleaning, disinfection against bacteria, or against mold/mildew.
3. On the proposed label, you must change "E. coli 0157:H7" to "E. coli O157:H7".
4. On page one of the product label, you must remove the graphic of your other product "Ultra Clorox". This graphic implies that the two products have the same efficacy, and is therefore misleading.
5. Revise the Precautionary Statements to read as follows: "Causes substantial but temporary eye injury and skin irritation. Do not get in eyes, on skin or on clothing. For sensitive skin or prolonged use, wear gloves. Harmful if inhaled. Avoid breathing vapor and use only in well-ventilated areas. May be harmful if swallowed." The statement "Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease" is currently unjustified by data and must be deleted.
6. In accordance with PR Notice 2007-4, the Agency defines "refillable" as follows:

"Refillable container" means a container that is intended to be filled with pesticide more than once for sale or distribution. The registrant determines whether a container is intended to be refilled for sale or distribution (in which case it is a refillable container) or if it is not intended to be refilled for sale or distribution (in which case it is not a refillable container) and implements its decision by labeling the container appropriately. This decision also would impact packaging design, packaging material, and distribution and marketing plans.

Please consider whether your containers meet our definition of refillable. If it is not your intention for this product to be marketed in containers which are returned to the distributor for refill and resale, then delete the language relevant to refillable containers, within the Storage and Disposal statement.
7. You must revise all Storage and Disposal language for Nonrefillable containers to include the following statement: "Nonrefillable container. Do not refill or reuse this container."
8. You must move the "Directions for Use" heading and accompanying advisory statement to the top of page two.
9. Should you wish to add/retain a reference to the product or company's website on your label, please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

10. You must delete the claim "Pool and outdoor areas" from page three of the label. This claim is too vague and can imply use sites other than those registered for this product.

A stamped copy of the labeling, accepted with comments, is enclosed. Submit one (1) copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Henson at (703) 308-6345.

Sincerely,

for Wanda Henson

Emily H. Mitchell
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Note: **Bold, italicized text is information for the reader and is not part of the label.** [Bracketed information is optional text.]
Underlined text is new. Strike-through (text) means removed.

EPA Reg. No. 05513-24 Tilex Page 1 of 4

ACCEPTED
 with COMMENTS
 EPA Letter Dated:

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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended, for the pesticide,
 registered under EPA Reg. No.

5813-24

TILEX®



Active Ingredient:
 Sodium Hypochlorite 2.40%
 Other Ingredients: 97.60%
 Total: 100.00%

(Yields 2.28% available chlorine)

KEEP OUT OF REACH OF CHILDREN.

WARNING: Eye irritant. Use only in
 well ventilated areas.

SEE BACK LABEL -or- PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS.

NET WT _____

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.

WARNING: Causes substantial but temporary eye injury and can irritate skin. For sensitive skin or prolonged use, wear gloves. Do not get in eyes or on clothing. Vapors may irritate. Use only in well ventilated areas. Avoid prolonged breathing of vapors. **Not recommended for use by persons with heart conditions or chronic respiratory problems such as asthma, emphysema or obstructive lung disease. (this statement will appear in color)** Due to irritating nature, may be harmful if swallowed.

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 eyes. **IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. **IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glassful of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor for further treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

PHYSICAL AND CHEMICAL HAZARDS: This product contains bleach. Do not use or mix this product with other household chemicals such as products containing ammonia, toilet bowl cleaners, rust removers, vinegar or acid. To do so will release hazardous gases.

Residential/Household uses (16 fl oz, 32 fl oz RTU spray)

STORAGE AND DISPOSAL:

Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration. Refill only with this product. [Please] recycle empty container or discard in trash.

Residential/Household uses (64 fl oz direct application/dilutable non-spray)

STORAGE AND DISPOSAL:

Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container. [Please] recycle empty container or discard in trash.

Professional/Institutional uses (32 fl oz RTU spray)

STORAGE AND DISPOSAL:

Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration. Refill only with this product. [Please] recycle empty container or discard in trash.

Professional/Institutional uses (64 fl oz, 128 fl oz direct application/dilutable non-spray)

STORAGE AND DISPOSAL:

Store this product in a cool [dry] area, [away from direct sunlight and heat] to avoid deterioration. In case of spill, flood areas with large quantities of water. Product or rinsates that cannot be used should be diluted with water before disposal in a sanitary sewer. Do not reuse empty container. [Triple rinse promptly, then] [please] recycle empty container or discard in trash.



Contains No Phosphorus.

[Best If Used By Date Below:]

EPA Reg. No. 5813-24, EPA Est. No. 5813-CA-3,
 CA-4, CA-5, GA-1, PR-1, 71106-GA-1, GA-2, 71681-
 IL-1, IL-2, GA-1, 82427-GA-1

(Actual EPA Est. No. in code below)

U.S. Patent Pending

Questions or comments[?]: [Call toll free] 1-800-227-1860 (in the US)
 -or- (787) 641-4943 (in Puerto Rico) [or visit www.tilex.com].

Mfd. for & © 2007 The Clorox Company, 1221 Broadway, Oakland, California 94612
 [and Dist. by & © XXXX Clorox Commercial Company, [Ave. Chardon, #350,
 Torre Chardon, Suite 320,] [San Juan, PR 00918].

(bracketed text for Puerto Rico only) Made in USA -or- Made in Puerto Rico

R1239-17.1

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EPA Reg. No. 05813-24 Tilex Page 2 of 4

TILEX®

AVOID PROLONGED BREATHING OF VAPOR

Use in well ventilated areas. Open windows and turn on fans before use. If the vapors bother you, leave the room while this product is working. For sensitive skin or prolonged use, wear gloves. Do not mix with Tilex® Soap Scum Remover -or- Tilex® Soap Scum and Bathroom Cleaner -or- Lestoil® Baño.

[Refill only with this product]

Alternate for Refill Bottle: To Refill [Spray Bottles]:

- | | | | |
|---|--|--|--|
| <p>Remove</p> <p>1. Remove trigger sprayer -or- cap from empty bottle.</p> | <p>Pour</p> <p>2. Unscrew cap on refill and pour contents directly into empty bottle.</p> | <p>Use</p> <p>3. Replace trigger sprayer and use as you normally would.</p> | <p>-or-</p> <p>[Remove trigger sprayer from empty bottle,] unscrew cap and transfer your trigger to this bottle.</p> |
|---|--|--|--|

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

HOUSEHOLD USE:

For non-foaming trigger:

TO REMOVE MILDEW STAINS: Turn sprayer nozzle to SPRAY position. Spray, wait until stains disappear and rinse. Heavy mildew buildup may require longer contact time, or two cleanings.

For foaming trigger:

TO REMOVE MILDEW STAINS: Turn nozzle to FOAM -or- FOAM-SPRAY -or- [For tough jobs,] turn nozzle to FOAM-STREAM [position] (*trigger has "foam-stream" and "foam-spray" listed on the nozzle*). Spray 6-8 inches from surface until surface is thoroughly covered. Allow foam to deeply penetrate mildew and problem areas. Wipe with a wet sponge or cloth, and rinse. Heavy mildew buildup may require longer contact time, or two cleanings. If excess foam dries on nozzle, rinse with warm water.

For both the foaming and non-foaming triggers:

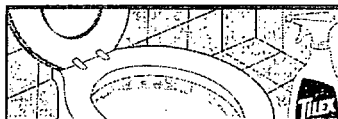
TO DISINFECT AND KILL MOLD & MILDEW ON HARD, NONPOROUS SURFACES such as glazed ceramic tile: Spray surface until thoroughly wet, let stand 5 minutes, and rinse.

TO KILL MOLD & MILDEW ON HARD, POROUS SURFACES such as grout and cement: Spray surface until thoroughly wet, let stand 10 minutes, and rinse. [Repeat application.]

TO CLEAN SOAP SCUM: Spray, wait a few minutes, wipe with sponge. Heavy soap scum or mildew buildup may need two cleanings. This product may not be able to remove soap scum and mildew embedded in hard water deposits, old grout or silicone caulking. **FOR SOAP SCUM PROBLEMS:** Use Tilex® Soap Scum Remover or Tilex® Soap Scum and Bathroom Cleaner or Tilex Bathroom Cleaner.

Works on grout, [bath]tubs, toilets, fiberglass, shower doors, vinyl curtains, counters -or- countertops, sinks, glass, plastic, glazed ceramic tile, unglazed ceramic tile, no-wax floors, basement floors, windowsills, refrigerator seals, and under the sink. Rinse immediately after use on rubber, plastic and vinyl. Avoid prolonged contact with metal and old porcelain as this product can react with these materials and leave a "rusty" stain. Do not use on wood or painted surfaces unless you plan to refinish or repaint them. This product may not be able to remove mildew embedded in hard water deposits, old grout or silicone caulking. Avoid contact with aluminum, clothes, fabric, carpet or paper surfaces as they will discolor. **BIG JOBS:** Tilex can effectively clean many household surfaces. For convenience, use the turret top or refill your Tilex sprayer bottle.

WHERE TO USE:



TO CLEAN AND DISINFECT TOILET BOWLS:
 Flush toilet and add 1 cup Tilex to bowl. Brush to thoroughly wet all surfaces including under rim. Let stand 5 minutes before flushing.



FLOORS: Mop washable floors including no-wax floors, linoleum, vinyl and ceramic tile with 1 cup Tilex per gallon of warm water. Rinse for best shine.



CEMENT POOL AREAS: Apply liberally (full strength) and rinse. **VINYL AND PLASTIC OUTDOOR FURNITURE:** Sponge on full strength and rinse immediately.

ACCEPTED
 with COMMENTS
 EPA Letter Dated:

JUL 13 2009

R1239-17.1

Under the Federal Insecticide,
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EPA Reg. No. 05813-24 Tilex Page 3 of 4

TILEX

Cleaning/Miscellaneous Claims

• New [!] *to be used as a claim descriptor only for the first 6 months of product on shelf*

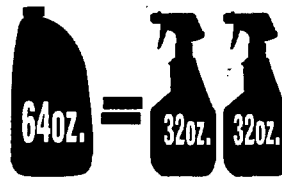
- 2-in-1 trigger [option]
- [40oz.] [44oz.] for the 32oz. price!
- Attacking Foam
- Bathrooms, sinks and faucets and floor areas
- [Be] [Get] Refill SmartTM[!]
- Bleaches away stains
- Brilliantly cleans [tile, grout, surfaces] before your eyes[!]
- Brilliantly whitens [tile, grout, surfaces] before your eyes[!]
- Brilliantly whitens [tile, grout, surfaces] for an intense clean[!]
- Check out the new price!
- Cheaper than [two] [2] 32 fl oz trigger[s] [sprays]*
- Clinging Foam
- Commercial solutions
- Contains bleach
- Cuts through -and/or- [starts to] dissolve[s] soap scum [on bathroom surfaces]
- [Deep Penetrating Foam]
- [Deep] [Penetrating] Foam clings to mildew stains
- [Deep] [Penetrating] Foam provides [great] control to reach mildew stains even in cracks -and/or- crevices -and/or- corners
- Dissolves[s] soap scum -and/or- [other] tough [bathroom] soils -and/or- stains
- Dual Action Trigger
- Dual Action Trigger provides spray and foam options -or- settings
- Dual Action Trigger provides spray for [broad] coverage and foam for control
- [Economy -or- Convenient] refill
- Economy size
- Extreme Foam
- Fills -or- equal to [two] [2] 32 fl oz trigger[s] [sprays]§
- [Foam] attacks [mildew stains] deep down
- Foam holds -or- stays [long(er)] on tough mildew stains
- [Foam] penetrates soap scum -or- grime [and bleaches away stains]
- Foam Sticks to Mildew Stain[s]
- Foam option -or- setting
- Foam or spray
- Foaming action attacks [mildew stains] deep down [for a powerful clean]
- Foaming Action for a Powerful Clean
- Foaming trigger [option -or- setting] for a deep clean
- Foaming trigger for control
- Just spray and wipe; no scrubbing required!
- Lavender Scent
- Learn more at [Tilex.com] [CleanFreak.com] [proudtobeacleanfreak.com] [friendsofclean.com] [proudtoclean.com]
- Lemon Fresh Fragrance
- Lemon Fresh [scent]
- Leaves no residue
- Low price [compared to our previous 32 oz. price]!
- Mama's got the magic of CloroxTM
- More Savings, Less Waste[!][!]
- New -and/or- [Improved] Thicker Foam
- [Now] choose Foam or Spray
- Powerful Cleaning Foam
- Sudsing -or- foaming action
- [Now] available in [this -or- a] convenient refill so you can reuse your trigger
- [Over] [insert %] more for the same price [as the 32 oz.]
- Plus [with] Clorox[®] Bleach
- Pool and outdoor areas
- Powers through soap scum -and/or- grime[!]
- Same [great] [Tilex] performance, [insert %] lower price [compared to our previous price]!
- Same [great] [Tilex] performance, now [insert %] cheaper [compared to our previous price]!
- Same [great] [Tilex] performance, now better value [compared to our previous price]!
- Saves a shopping trip††
- See it and believe it
- See the difference [Tilex makes]
- Six -or- 6 month supply[!][!]
- Thick Foam
- Two Ways to Clean
- Up to [a] 30% [discount] [cheaper] [free][!]*
- [Use as a] [Pourable] refill for this product -and/or- [multi-surface] cleaner
- [Value] [Economy] [Budget] size -or- refill
- [Value] [multi] [twin] pack
- Watch Tilex clean
- With bleach

* [when compared to] [vs.] 32 fl oz Tilex[®] trigger [spray] in most stores, based on average retail price -and/or- volume

†† [when compared to] [vs.] purchasing one 32 fl oz Tilex[®] trigger spray

‡‡ 40% less plastic [when compared to] [vs.] [in comparison to] two -or- 2 32 fl oz Tilex[®] trigger sprays

§ of this product



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EPA Reg. No. 05813-24 Tilex Page 4 of 4

TILEX

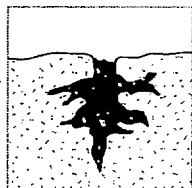
Pesticidal Claims

- Destroys mold and mildew in [just] 5 minutes
- Destroys mold, mildew and bacteria [in just 5 minutes]
- Disinfects as it cleans big jobs
- Disinfects as it kills [destroys] [eliminates] [wipes out] [removes] mildew
- Disinfects as it kills [destroys] [eliminates] common household mold, mildew and bacteria
- Disinfects with bleach
- Easily removes mildew, mold and bacteria from grout and also quickly destroys and kills them in hard-to-clean areas such as caulking, corners and crevices, without scrubbing
- Easily removes tough mildew and mold from grout
- Eliminates mold and mildew in [just] 5 minutes
- Eliminates mold, mildew and bacteria [in just 5 minutes]
- Even mold isn't too tough for Tilex!
- Get rid of mold
- Got Mold? Kill [Destroy] [Eliminate] [Wipe out] [Remove] it with Tilex!
- Kills CA-MRSA**
- Kills [Destroys] [Eliminates] [Wipes out] [Removes] mold, mildew and bacteria as it cleans
- Kills [Destroys] [Eliminates] [Wipes out] [Removes] visible mold
- Kills [Destroys] [Eliminates] 99.9% of household molds
- Kills [Destroys] [Eliminates] 99.9% of household molds and mildew in just 5 minutes
- Kills [Destroys] [Eliminates] and removes mold and mildew
- Kills [Destroys] [Eliminates] mildew without scrubbing
- Kills [Destroys] [Eliminates] mold and mildew
- Kills [Destroys] [Eliminates] tough mildew without scrubbing
- Kills [Destroys] [Eliminates] tough mold and mildew without scrubbing
- Kills [Destroys] [Eliminates] tough mold, mildew and bacteria in just 5 minutes
- Kills [Eliminates] and destroys mold and mildew
- Kills mold and mildew in [just] 5 minutes
- Kills mold, mildew and bacteria [in just 5 minutes]
- Kills most common household molds
- Lifts off and cleans soap scum to penetrate, kill and destroy mold, mildew and bacteria
- Mold is alive. Kill [Destroy] [Eliminate] [Wipe out] [Remove] it with Tilex!
- Mold Killer!
- Not only destroys mold and mildew, but also destroys and removes the mold spores
- Not only eliminates mold and mildew, but also destroys and removes the mold spores
- Not only kills mold and mildew, but also destroys and removes the mold spores
- Penetrates to eliminate and destroy tough mold, mildew and bacteria at its source
- Penetrates to kill and destroy tough mold, mildew and bacteria at its source
- Proven to kill most common household molds!
- This product kills Staphylococcus aureus (Staph) [ATCC 6538], Streptococcus pyogenes (Strep) [ATCC 9342], Trichophyton mentagrophytes (Athlete's Foot Fungus) [ATCC 9533], Aspergillus niger (mildew) [ATCC 6275] -or- [ATCC 16404], Salmonella choleraesuis -or- Salmonella enterica (Salmonella) [ATCC 10708], Pseudomonas aeruginosa (Pseudomonas) [ATCC 15442], Penicillium chrysogenum (Penicillium) [ATCC 10106], Alternaria alternata [ATCC 6663], Cladosporium herbarum [ATCC 28987], Mucor bainieri [ATCC 42642], Community Associated Methicillin Resistant Staphylococcus aureus [CA-MRSA**] [NARSA NRS123] [Genotype USA 400] -or- CA-MRSA**, Community Associated Methicillin Resistant Staphylococcus aureus [CA-MRSA**] [NARSA NRS384] [Genotype USA 300], Escherichia coli O157:H7 [ATCC 35150], ESBL (Extended Spectrum Beta Lactamase) producing Escherichia coli (ESBL producing E. coli) [ATCC BAA-196]
- Tilex doesn't just clean [the] stains, it kills [destroys] [eliminates] [wipes out] [removes] [the] mold!
- Watch mold disappear before your eyes
- Works [Kills mold] on all [hard, porous and nonporous] bathroom surfaces
- You've got mold. Kill [Destroy] [Eliminate] [Wipe out] [Remove] it with Tilex.

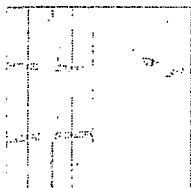
**Community Associated Methicillin Resistant Staphylococcus aureus

For use with Formula A07 and foaming trigger:

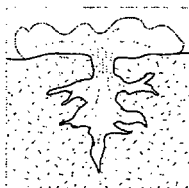
- Attacks mildew at its roots
- Gets into and eliminates mildew even in hard to clean places – without scrubbing
- Kills mold and mildew at its roots
- Kills mold and mildew in hard to clean areas [places] [such as caulking, corners, crevices, cracks]
- Penetrates to kill and destroy tough mold, mildew and bacteria at its source
- Penetrates to kill mildew in hard to clean places
- [Seeks out and] kills mildew at its roots
- [Seeks out and] kills mildew even in hard to clean places
- This product has a penetrating foam that seeks out and kills mildew even in tile grout, caulking and corners
- This product penetrates deep beneath the surface
- With [Deep] [Penetrating] Foam



Mildew grows deep in cracks.



Foam penetrates deep to [kill] [get] mildew at its roots.



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