# ITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



# **EPA** United States Environmental Protection Office of Pesticide Programs Agency

JAN 14 2010

Jamie Quon The Clorox Company c/o PS&RC P.O. Box 493 Pleasanton, CA 94566-0803

FILE CORY

Subject:

PRIA (D-419577)

Tilex

EPA Registration No. 5813-24

Application Dated: August 28, 2009 Receipt Dated: August 31, 2009

Dear Mr. Quon:

The current submission addresses EPA comments from the accepted with comments letter dated July 13, 2009, which served as the Comprehensive Labeling Review for this registration.

The following PRIA amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

# Response to EPA comments from the Comprehensive Label Review:

- 1. The directions for use will remain unchanged. Tilex is a ready-to-use spray product. To disinfect, the directions for use instruct the user to spray until thoroughly wet and let stand 5 minutes. This is the appropriate use dilution.
- 2. The claim for "pool and outdoor areas" was deleted from page three of the label."
- 3. Supplemental information is provided for the root penetrator claims in a document entitled "Supplemental Information for Root Penetrator Claims," and in Volume II and III.
- 4. Clarification was provided for the claim "To clean" in the cement pool areas on the label.
- 5. Changes were made to the label to make the "O" in E. coli O157:H7" clear to the reader.

- 6. Revisions were made to the graphic of the Clorox bleach bottle to add the words, "Contains Bleach".
- 7. Retaining the Precautionary Statements as stated on the label. Required updates were made to the Storage and Disposal Statement in accordance with PR Notice 2007-4.
- 8. Moved the "Directions for Use" heading and accompanying advisory statement to the top of page two of the label
- 9. Claims retained on the label by The Clorox Company are as follows:
  - -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 even in hard to clean places
  - -This product penetrated deep beneath the surface

# **Agency Response:**

- 1. The claims against "household molds" are supported by efficacy data against the following molds: Alternaria alternate, Aspergillus niger, Cladosporium herbanum, Mucor bainieri, and Penicillium chrysogenum. The claims "Kills 99.9% of household mold", "Kills 99.9% of household mold and mildew in just 5 minutes", and "Kills most common household molds" are acceptable.
- 2. The following observations were made from the references provided:
  - No titration was done in the crevices or cracks to prove that chemical gets deep down in the cracks.
  - The papers are about new way or method of titration with the ability of the combination surfactants to stay longer on surfaces.
  - Foamy product appear longer on surfaces what may help chemical to get dip in crevices where mold grows or to reach mold roots.

Based on the Agency's review of the provided documentation, the claims "Attacks mildew at its roots," "Kills mold and mildew at its roots," and "Seeks out and kills mildew even in hard to clean places" are acceptable.

- 3. The label proposed claim, "Seeks out and kills mildew even in hard to clean places," and "This product penetrated deep beneath the surface," are unacceptable. As stated above, no titration was done in the crevices and cracks to demonstrate penetration deep down in cracks. Therefore, these statements have been removed from the proposed label.
- 4. The proposed label claim "Watch mold disappear before your eyes" is unacceptable. Certain aspects of mold are microscopic, and therefore not visible with the unaided eye. Therefore, this claim has been removed from the proposed label.
- 5. The Agency accepts The Clorox Company's responses 1-8 as stated above.

# **General Comments:**

A stamped copy of the labeling accepted with conditions is enclosed. Submit one copy of your final printed labeling 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

Wanda Y. Hensør

Acting Product Manager – Team 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.



### 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. Do not reuse or refill except as described in the directions for use. 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. Nonrefillable container. Do not refill or reuse this container. [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, 71681IL-1, IL-2, GA-1, 82427-GA-1
(Actual EPA Est. No. in code below)
U.S. Patent Pending

#### 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. Do not reuse or refill except as described in the directions for use. 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. Nonrefillable container, [Triple rinse promptly, then] [please] recycle empty, container or discard in trash.

Questions or comments[?]: [Call toll free] 1-800-227-1360 (*in the US*) o c c c c c o-or- (787) 641-4943 (*in Puerto Rico*) [or visit www.tijex.gom]. o of c c c of Mfd. for & © 2007 The Clorox Company, 1221 Broadvay, Gakland, California 94612 [and Dist. by & © XXXX Clorox Commercial Company, [Ave. Chardon, #350, Torre Chardon, Suite 320,] [San Juan, PR 00918].

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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.

#### 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]:

1. Remove trigger sprayer -or- cap from empty bottle.

2. Unscrew cap on refill and pour contents directly into empty bottle.

### Use

3. Replace trigger sprayer and use as you normally would.

(Remove trigger sprayer from empty bottle,] unscrew cap and transfer your trigger to this bottle.

#### 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 "loam-stream" and "loam-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.



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.

# WHERE TO USE:



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.



TO CLEAN CEMENT, POOL, AREAS: Applyolicerally (full strength) and rifise. WINYL AND PLASTIC OUTDOOR FURNITURE: Sponge on full strength and rinse immediately. 

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#### Cleaning/Miscellaneous Claims

ullet 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 Smart[™][!]
- · 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/orstains
- 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 Clorox™

- 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
- 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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#### 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 Killer¹
- 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 soores
- 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], ¹Trichophyton mentagrophytes (Athlete's Foot Fungus) [ATCC 9533], ¹Aspergillus 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], ¹Alternaria 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!
- · 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 even in hard to clean places
- This product has a penetrating foam that seeks out and kills ຕົ້າໄດ້ຮັ້ນ even in tile grout, caulking and corners
- · With [Deep] [Penetrating] Foam



Mildew grows deep in cracks.



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



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