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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

> OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

April 27, 2005

W.A. Hawkins Jr., Ph.D. Registration Specialist II **S.C. Johnson & Son, Inc.** 1525 Howe Street Racine, WI 53403

Subject: Oscar EPA Registration No.4822-539 Application Date: December 7, 2004 Receipt Date: December 12, 2004

Dear Dr. Hawkins:

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 subject to the conditions listed below.

## Proposed Label Amendment

Label amendment to add biofilm claims on hard non-porous surfaces

Revised use directions

## Conditions:

The submitted efficacy data support the use of this product to remove biofilm on surfaces which do not undergo routine shear stress (static biofilms). The surfaces supported by the static biofilm efficacy data are the ones listed on the label except for the surfaces listed in 1(b) below. The following MRID #s were assigned to the submitted efficacy data:

MRID 464271-01 MRID 464271-02 MRID 464271-03 1. Data are required to confirm that this product is efficacious in controlling biofilm on surfaces that routinely undergo fluid stress. Consequently, the following are required.

a) A protocol which would be used to develop efficacy data to demonstrate biofilm control using a drip flow reactor must be submitted to the Agency for approval within 12 months from the date of this letter.

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b) Efficacy data must be submitted within 7 months following notification of Agency approval of the above protocol. The efficacy data must be found acceptable or the following surfaces must be removed from the label:

Basins Bathroom sink Fiberglass tubs, shower surrounds, and sinks Plastic and vinyl shower doors Shower doors Shower fixtures Shower walls Showers Sinks Urinals

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2. Labeling Comments: The following label changes must be made before you release this product for shipment bearing the biofilm claims:

a) Use of the phrase "biofilm sanitizer" is not acceptable. The term "sanitizer" must be replaced with another term. A suggested phrase is "controls biofilm".

b) The Agency has traditionally limited use of the term "slime" on pesticide labeling to non-public products. For public health products, the Agency prefers that the term "biofilm" be used since efficacy data are required to support this claim for certain use sites. Therefore to preserve this distinction, anywhere on this label the term "slime" is used it must also be associated with the term "biofilm".

c) On page 2 of the proposed label remove the term "(1<sup>st</sup>) (first)" from all of the claims listed on the label.

d) On page 1 of the proposed label the claim "slows down biofilm build up" must be removed. This claim implies prevention and inhibition of biofilms and has not been tested or proven.

e) On page 1 of the proposed label, change "Seeks and Destroys bacteria and the slime they form" to read "Destroys bacteria and the slime they form". The term "seeks" implies that the agent itself can locate and search for bacteria, this claim has not been tested.

f) On page 2 of the proposed label, eliminate the phrase "Kills bacteria deep down in the biofilms (,) (not just the top layer)." This claim has not been proven; no microscopy has been done to show that several layers of extracellular polymeric substance (EPS) exist, and that the product penetrates through many of them.

g) A clear distinction must be made with the layout and wording of the final label between biofilm sanitization, and surface sanitization of unattached organisms. The contact times for each, 5 minutes and 1 minute respectively, are not to be confused.

# **General Comments**

A stamped copy of the accepted labeling is enclosed.

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If the above conditions listed in this amended registration acceptance are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Mark Hartman Acting Branch Chief Regulatory Management Branch II Antimicrobials Division (7510C)

Enclosure

## A Bathroom Cleaner, Sanitizer (Biofilm Sanitizer) and Mildewstat

Removes Soap Scum (and) Kills 99.9% of bacteria\* (in 1 minute)

Active Ingredient: L-Lactic Acid	2.0%
Other Ingredients:	<u>98.0%</u>
Total:	100.0%

## **KEEP OUT OF REACH OF CHILDREN**

CAUTION: See additional precautions on back panel.

#### Biofilm Claims:

Scrubbing Bubbles (Max) (Soap Scum Remover) (Bathroom Cleaner) (with) (Bio-Remover<sup>™</sup>): Cleans biofilm away

Cleans away bacterial grunge or slime

Cleans bacterial grunge in biofilm

Cleans so thoroughly it slows down biofilm build up (kills bacteria that form slime)

Cuts through the grungy biofilm buildup to kill bacteria where they live and hide

Cuts through the slime that can harbor bacteria

(Seeks and) Destroys bacteria and the slime they form

Gets to the source of the bacteria layers lurking in your home and wipes it out

(Formulated to) (Clean)(s) (soap scum) (and) (Kill)(s) (Eliminate)(s) (Reduce)(s) (Remove)(s)

(Destroy)(s) (Attack)(s) (99.999% of (99.9% of) (in 5 minutes) (the)

- bacteria in (slimy) biofilm
- bacteria in slimy buildup
- bacteria living in (slime) (called) biofilm
- bacteria growing in biofilm
- bacteria living and growing in biofilm
- bacteria protected by biofilm
- bacteria protected by slimy buildup
- bacteria in organic slime
- bacteria under the slime
- bacteria within the slime
- bacteria where they hide in biofilm
- bacteria hidden in soap scum
- bacteria under the soap scum

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- bacteria in (the) grungy buildup

## - greater than 99.999% of bacteria in biofilm

- protected bacteria living in biofilm

- surface associated bacteria

- 99.999% of surface associated bacteria

-household surface associated bacteria

Eliminates slimy buildup

Kills bacteria deep down in biofilms (,) (not just the top layer)

Kills bacteria where they hide (!)

Kills the bacteria under the buildup even before you see it (in your home)

Loosens up the slime that can harbor bacteria

Penetrates biofilm and wipes out bacteria (!)

Penetrates biofilm, killing the bacteria living there

Penetrates deep into biofilm to kill bacteria embedded in it

Penetrates the biofilm and kills bacteria (!)

Penetrates the bacterial layers for a deep down clean

Penetrates the grungy biofilm buildup to kill bacteria living there

Penetrates the (slime) (film) and kills bacteria (!)

Penetrates the slime that can harbor bacteria

Penetrates slime and kills bacteria where they hide (- in biofilm)

Proven to penetrate the invisible biofilm layer on your bathroom surfaces

Reaches and kills 99.999% of embedded bacteria in biofilm

Slows down biofilm buildup

Specifically (designed) (formulated) to destroy bacteria in biofilm

The  $(1^{st})$  (first) bathroom cleaner that kills bacteria in biofilm The  $(1^{st})$  (first) bathroom cleaner approved to kill bacteria in biofilm The  $(1^{st})$  (first) bathroom cleaner (with) (that has) Bio-Remover<sup>TM</sup>)

The (1) (first) ballioon cleaner (with) (mat has) blo-Remover (\*\*)

The  $(1^{st})$  (first) bathroom cleaner that penetrates biofilm to kill bacteria

The  $(1^{st})$  (first) bathroom cleaner with biofilm claims

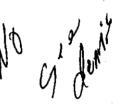
The (1<sup>st</sup>) (first) bathroom cleaner that kills the tough bacteria in biofilm

The  $(1^{st})$  (first) bathroom cleaner that penetrates the slimy biofilm and kills the bacteria where they hide

The (1<sup>st</sup>) (first) bathroom cleaner that penetrates the slimy, glue-like biofilm to kill (even) the toughest bacteria

The  $(1^{st})$  (first) bathroom cleaner that kills the slimy bacteria The  $(1^{st})$  (first) bathroom biofilm penetrator

Packaging Claims: Big (job) size Bigger size (package) (bottle) Economy size (New) (Improved) (fragrance) (scent) (!) (New!) (New) (Comfort) (Easy Grip) (Ergo) (Improved) (Trigger)



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(New) (ergonomic) (user-friendly) trigger makes (this product) even easier to use! (New) (Big) 32 oz. (Size) (Two) (2) Liter (Size) (!) Trial size (Available) Value (Pack) (Size) (X) (free) (more) (!) (X) at the (X oz.) price (!)

## Miscellaneous Statements/Claims:

Bottle made of XX% post-consumer recycled plastic Contains no abrasives, harsh acids or bleach Contains no (Chlorine) (,) (or) (Bleach) (,) (or) phosphates For old or worn surfaces, test on a small area before use Will not harm septic (systems) (tanks)

#### Fragrance/Scent Violators:

(Citrus) (Citrus Action) (Citrus Blast) (Citrus Blend) (Citrus Boom) (Citrus Energy) (Citrus Explosion) (Citrus Extreme) (Citrus Power) (Citrus Splash) (Citrus Surge) (Citrus Twist) (Citrus Ultra) (Citrus Zest) (Clean) (Fresh) (Light) (Lemon) (Lemon Zest) (Refreshing) (Unscented) (Orange) (Orange Action<sup>™</sup>) (Orange Twist) (Floral) (Grapefruit) (Scent) (!)

Marketing Claims: 1 minute sanitization A (new) tough cleaning formula An effective sanitizer for use in the bathroom Antibacterial bathroom leaner Antibacterial Action Antibacterial Formula (cleans and sanitizes) Bathroom (restroom) cleaner and sanitizer Bleach-free Cleans (and) (sanitizes) (deodorizes) Cleans and sanitizes (without harsh fumes) Cleans and shines without scratching (Cleans) (removes) (tough) soap scum(!) Cleans: Penetrating foam powerfully removes tough soap scum and grime (!) Cleans Soap Scum without scrubbing Cleans without scrubbing Complete clean (!) Cuts soap scum, hard water stains and shines bathroom surfaces Cuts through tough soap scum Deep penetrating antibacterial formula Deodorizes Dissolves tough soap seum on contact

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Does not contain bleach

Easily cleans tough (bathroom) (restroom) (dirt) (soil) (soap scum) (hard water) (stains) and sanitizes

Easily cleans tough greasy dirt and sanitizes

Easily cleans tough greasy (dirt) (grime) (fingerprints) and sanitizes

Easily removes soap scum (hard water stains) (and) (dirt)

Easy to use

Effective sanitizing has never been easier

Effectively cleans tubs, showers, basins, ceramic tile, stainless steel, chrome, fiberglass, vinyl and porcelain surfaces.

Eliminates odors

Fast, easy cleaning solution - one product for a variety of surfaces

For daily use

For everyday cleaning

For general (cleaning and) sanitizing of hard non-porous surfaces

For use on household surfaces

Freshens: (Orange Action<sup>™</sup>) (fragrance) deodorizes and leaves your bathroom smelling fresh! Great for use in your bathroom

Great on surfaces such as: (See List of Surfaces)

Guaranteed to clean or your money back (see back panel)

Heavy duty cleaner

Helps fight bacteria

Helps prevent cross-contamination of hard non-porous surfaces

Helps prevent (Reduces) cross contamination from treated surfaces.

Helps prevent bad (odors) (malodors) by cleaning, sanitizing and deodorizing the following surfaces: (See List of Surfaces)

Household bacteria killing formula

For (tough) (tougher) cleaning (!)

Inhibits mold and mildew in damp and musty places

Kills (99.9%) of bacteria\* in 1 minute

Kills (99.9% of) household bacteria\* in 1 minute

Kills household bathroom bacteria

Kills (removes) (99.9%) of Escherichia coli (and) Staphylococcus aureus and Klebsiella pneumoniae

Kills 99.9% of bacteria\* in 1 minute

Kills 99.9% of Staph (Staphylococcus aureus) and Klebsiella pneumoniae in 1 minute

Kills bacteria\* in (just) 1 minute

Kills bacteria that cause odors

Kills bacteria\* (found) on hard non-porous (bathroom) surfaces

Kills common household bacteria\*

Leaves (bathrooms) (your bathroom) clean and (shiny) (shining)

Leaves a brilliant shine (!)

Leaves a brilliant shine and a fresh, clean scent

Leaves hard, non-porous surfaces sanitized

Leaves your bathroom clean and fresh

Makes cleaning easy and sanitizes too

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Makes killing bacteria easy

Multi-surface (cleaner)

(New) Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) removes (tough) soap scum and bathroom grime (more powerfully) (more easily) than ever before!

No (visible) (smeary) (oily) residue (build up)

No harsh fumes

No-scratch formula

Now cleaning and killing bacteria is easier than ever before

(Now) The cleaning power of Scrubbing Bubbles (comes) with the invigorating scent of fresh (oranges)!

One-step cleaning and sanitizing

(Orange Action<sup>™</sup>) fragrance deodorizes and leaves your bathroom smelling fresh!

Penetrating foam thoroughly cleans and leaves behind a (brilliant) shine!

Powerful formula cleans and sanitizes

Perfect for cleaning up around the toilet

Powerfully removes tough soap scum (!)

Prevents the growth of mold & mildew\*\*

Effectively removes bacteria\*

Ready to use, convenient; the easy way to clean and sanitize toilet seats, toilet exteriors, and other non-porous surfaces

(Removes) (Gets rid of) soap scum (hard water stains)

Removes (hard water stains) (soap scum) (sanitizes), (deodorizes)

Removes Soap Scum

Removes tough soap scum easily (!)

Sanitizes (kills) common household bacteria\* (and prevents the growth of fungi\*\* (and) (or) mold)

Sanitizes (household) bathroom surfaces in 1 minute

Sanitizes and deodorizes

Sanitizes as it cleans

Sanitizes hard non-porous bathroom surfaces

Sanitizes in just (1) minute

S.C. Johnson has a cleaning solution for every room in your home

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) cleans and sanitizes the following surfaces: (See List of Surfaces)

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) is the convenient way to (clean) (and) (sanitize) bathroom surfaces

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) is the easy way to clean and sanitize

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) is the effective way to clean and sanitize

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) kills many types of (household) bacteria\* (and eliminates their odors)

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) kills the following bacteria: *Staphylococcus aureus* (Staph) (ATCC #6538), *Klebsiella pneumoniae* (ATCC #4352), *Escherichia coli* (E. coli) (ATCC #11229)

Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) thoroughly cleans (shines) (and) (sanitizes) (deodorizes). Specially formulated to attack (tough) soap scum, hard water stains and dirt Shines: Leaves behind a brilliant shine (!) Shines (and) (plus) kills household bacteria\* Specially formulated for a variety of surfaces Specially formulated for use daily (to clean bathroom soils such as soap, soap scum, toothpaste, hair spray, hair gel, cosmetics, shaving cream and hand and body lotion) Specially formulated for use in the bathroom Specially formulated to attack (tough) soap scum, hard water stains and dirt Starts killing bacteria on contact Such tough cleaning that it leaves no visible residue behind (!) The easiest way to keep your bathroom clean everyday The easy way to clean and sanitize The (easy) (effective) way to clean and sanitize This product is a mildewstat and will effectively inhibit the growth of mildew on hard nonporous surfaces The smart way to (kill) (remove) bacteria Tough cleaning formula (with a fresh scent) Tough cleaning never smelled so good Tough cleaning without the oily (smeary) residue (!) Tough on dirt and bacteria\*...Easy on You! Tough on dirt...Easy on you! Tough on soap scum Use in the bathroom Use Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>TM</sup>) to sanitize the following surfaces: (See List of Surfaces) Use throughout the bathroom Versatile cleaner for all of your bathroom surfaces Versatile cleaner that can be used throughout the bathroom We work hard so you don't have to!<sup>®</sup> When used as directed, Scrubbing Bubbles (Soap Scum Remover) (Bathroom Cleaner) (Max) (with) (Bio-Remover<sup>™</sup>) prevents build-up of soap scum Will not harm most surfaces With a bleach-free formula With a pleasant fragrance Won't scratch surfaces R Works (best) on soap scum (!) Works in 1 minute to kill 99.9% of (household) bacteria\*

\*Staphylococcus aureus (Staph) (ATCC #6538), Klebsiella pneumoniae (ATCC #4352), Escherichia coli (E. coli) (ATCC #11229)

\*\*Aspergillus niger (ATCC #6275)

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Surfaces: Works on multiple surfaces (Recommended for use on) (Effective on) (Effectively Cleans) (Cleans) (Sanitizes) (and) (Deodorizes) (hard, non-porous) bathroom surfaces (such as): Non-wood finished cabinets Basins -Bathroom sink Chrome Counter tops Diaper changing counters Diaper pails Doorknobs Enamel Faucets (Fiberglass tubs, shower surrounds and sinks) Floors Formica<sup>®</sup> Garbage cans Glazed porcelain Glazed ceramic tile Hand rails Light switches Plastic Plastic and vinyl shower doors Shower doors Shower fixtures Shower walls Showers Sinks Stainless steel Synthetic marble Toilet seats and exterior toilet surfaces Exterior toilet surfaces Trash cans Tubs Urinals Vanity tops Vinvl Walls Will not harm most surfaces

Will not harm most surfaces Not recommended for use on natural marble, brass, or varnished wood Spot test all other surfaces For old or worn surfaces, test on a small area before use Test on painted areas before using Will not scratch (bathroom surfaces)!

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in Apartments Bathrooms Day care centers Homes Hotels Malls Motels Nursing homes Public restrooms Residences Restrooms Schools

#### Soils:

(Specially formulated to remove) (Effective at removing) (Effective for cleaning) (Use to clean) (Removes) (bathroom soils) (such as):

Bath gel, Body lotion, Body wash, Conditioner, Cosmetics, Dirt, Fingerprints, Grime, Hair gel, Hair spray, Hand lotion, Hard water stains, Shampoo, Shaving cream, Shower gel, Soap, Soap scum, Toothpaste

#### DIRECTIONS FOR USE

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

# TO CLEAN:

1. Turn nozzle to ON position.

2. Spray 6-8 inches from surface. Cover all surfaces evenly. Allow foam to penetrate dirt and soap scum (for tough jobs, let stand for several minutes before wiping).

3. Wipe with a wet cloth or sponge, then rinse thoroughly with water.

TO KILL 99.9% OF BACTERIA ON HARD NON-POROUS SURFACES: Spray surface until thoroughly wet. Let stand for 1 minute. Then wipe. For heavily soiled areas a pre-cleaning is required.

TO SANITIZE (KILL (99.999% of) BACTERIA IN BIOFILMS ON HARD, NON-POROUS SURFACES: Spray surface until thoroughly wet. Let stand for 5 minutes. Then wipe. Repeat treatment as needed for heavy soil / heavy buildups.

TO INHIBIT AND PREVENT THE GROWTH OF MOLD & MILDEW ON HARD NON-POROUS SURFACES: Spray surface until thoroughly wet. Let stand for 5 minutes. Then wipe. Reapply as necessary.

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Good ventilation during use is recommended.

Never use or mix with bleach-containing products as hazardous fumes may be released. Unplug small electrical appliances before (use) (cleaning) (sanitizing) (them) with this product.

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

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. Call a poison control center or doctor for treatment advice.

(STORAGE & DISPOSAL:) STORAGE: Store out of reach of children. DISPOSAL: Do not reuse container, discard in trash.

EPA Reg. No. 4822-539 EPA Est. No. (4822-WI-1), (71681-IL-1), (71681-IL-2)

Questions? Comments? Call 800-558-5252 or Write Helen Johnson ©(2002) (2003) (2004) (2005) (2006) S.C. Johnson & Son, Inc. Racine, WI 53403-2236 U.S.A. All Rights Reserved Visit our website at: <u>www.scjohnson.com</u>, <u>www.scrubbingbubbles.com</u>) S.C. Johnson

A Family Company

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Option ... Pictograms:

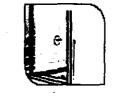
Tub & Tile



Sink & Counter



Shower Doors & Chrome



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[Based on the EPA stamped accepted label dated October 22, 2004.]