

75277-2

3/11/2014

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

J. Michael Kelley, PhD.
Toxcel Toxicology and Regulatory Affairs
7140 Heritage Village Plaza
Gainesville, VA 20155-3061

MAR 11 2014

Subject: FREAK
EPA Registration No.: 75277-2
Notification Date: February 12, 2014
EPA Receipt Date: February 12, 2014

Dear Dr. Kelley,

This letter acknowledges receipt of your notification submitted under the provisions of FIFRA section 3(c) 9 and PR Notice 98-10.

Proposed Notification

- Modifying the language from "Do not use on marble" to exclude use on all "Natural stone". Granite has also been removed as a suitable surface.
- Adding "Spearmint and "Wildflower" as optional fragrance descriptors.

General Comments

Based on a review of the submitted materials, to modify the language "Do not use on" statement and add optional fragrance descriptors are **acceptable** and apart of the record on file for future reference.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Jacqueline Hardy", is written over the typed name.

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide – Section 1

1. Company/Product Number 75277-2	2. EPA Product Manager Jacqueline Campbell-McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FREAK	PM# 34	
5. Name And Address Of Applicant (Include ZIP Code) Method Products Inc. 637 Commercial Street San Francisco, CA 94111 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name

Section II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain Below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)**Notification to exclude use on "natural stone" for FREAK (EPA Reg. No. 75277-2).**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per Container			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container 12 to 60 oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other <u>Plastic label glued</u>			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ryan Williams		Title Director of Regulatory Affairs		Telephone No. (Include Area Code) 415-746-1717	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Authorized Representative for Method Products			
4. Typed Name J. Michael Kelley, PhD		5. Date 12 February 2014			

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toXcel

Toxicology & Regulatory Affairs

7140 Heritage Village Plaza

Gainesville, VA 20155

USA

Phone: (703) 754-0248

Fax: (703) 310-6950

HAND-DELIVER

12 February 2014

Jacqueline Campbell, PM-34
Antimicrobial Division (7510P)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

RE: Notification for **FREAK** (EPA Reg. No. 75277-2)

Dear Ms. Campbell:

On behalf of Method Products, Inc. of San Francisco, California, we are submitting a notification to update the language from "Do not use on marble" to exclude use on all "natural stone". Granite has also been removed as a suitable surface, pursuant to this updated exclusion. In addition, "spearmint" and "wildflower" have been added as optional fragrance descriptors, which are currently components of alternate formulations on file with the Agency.

The following documents are enclosed:

- 1) EPA Form 8570-1
- 2) One copy of the proposed label with modifications marked
- 3) One copy of the proposed new Master Label (dated February 12, 2014)
- 4) CD copy of the label

If you have any questions or require additional information, do not hesitate to contact me by phone at 703-754-0248 x112 or by email at Mike.Kelley@toxcel.com.

Sincerely,



J. Michael Kelley, PhD
Authorized Representative for Method Products, Inc.

cc: Ryan Williams (Method)
Geetha Solheim (Method)

cc: Ryan Williams (Method)
Geetha Solheim (Method)

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[optional language]

{note to agency}

FREAK

Hard surface disinfectant and/or sanitizer

Active Ingredients: Citric Acid	5.0%
Other Ingredients	95.0%
Total	100.0%

NOTIFICATION
Date Reviewed: 3/11/14
Reviewed By: [Signature]

[CAUTION]
KEEP OUT OF REACH OF CHILDREN

EPA Reg. No. 75277-2

EPA Est. No

Net Contents XX

Method Products Inc

San Francisco, CA 94111

Questions:

Phone [(xxx) xxx-xxxx]

Visit: [www-xxxxxxxxxxx-com]

{Precautionary Statements: toxicity category IV; OPTIONAL}

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. 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.

C C C C C C
C C C C C C
C C C C C C
C C C C C C
C C C C C C
C C C C C C

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

Cleaning Instructions: [Twist nozzle to on.] Spray surface [onto soils]-and- [rub][wipe][scrub] clean.

[optional language]

{note to agency}

Sanitizing Instructions (Non-food Contact):

To Sanitize Non-Food Contact Hard Non-Porous Surfaces: Spray until thoroughly wet. Let stand [for] 5 minutes [before wiping] [and wipe]. For heavily soiled [areas] [surfaces], [a] precleaning [step] is required.

Claims:

[Kitchen] Sanitizer

[Antibac] [Antibacterial]

[Cleans] [shines] [sanitizes] [kitchen] [household] [surfaces] [and/or] [fixtures] [throughout the home] [house]

Kills [99.9%] of [*Staphylococcus aureus*] [*Enterobacter aerogenes*] [on hard, nonporous surfaces] in 5 minutes

Kills [household] bacteria [and sanitizes without bleaching]

Kills 99.9% of [household] bacteria in 5 minutes

One step cleaning and sanitizing

Storage and Disposal: Nonrefillable container. Store airtight at room temperature. Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard in trash.

Disinfecting Instructions:

To Disinfect: Spray [on surface][until thoroughly wet]. Let stand –or–leave for 10 minutes. Wipe [with [paper towel] –and/or–[microfiber][clean][dish] towel –and/or– [cloth]].

Claims:

Disinfect

[Easily] Clean[s][and/or][disinfect[s]] [in][one easy step]

Kills germs* [- including] [*Staphylococcus aureus*] [Influenza A Flu Virus], [Rhinovirus] [*Salmonella enterica*]

[optional language]
{note to agency}

Toilet Bowl Instructions:

{This section is for CSF alternate formulations 10 - 13}

Cleaning Instructions:

To Clean [and deodorize]: [Twist nozzle to on-or-twist to open.][Spray-or-squirt] [product][gel] under rim [and cover the inside of the toilet bowl evenly]. [Wait [10 minutes] for product to do its thing.][Brush. Flush.][Done.]

Sanitizing Instructions:

To kill [99.9% of] bacteria-or-To sanitize: Empty toilet bowl, spray-or-squirt [product][gel][under rim]to cover surface. Wait 5 minutes, then brush and flush. For heavily soiled areas a pre-cleaning step is required.

Disinfecting Instructions:

To disinfect: Empty toilet bowl [of water][and any other contents], spray-or-squirt[product][gel] to cover surface. Wait 10 minutes, [then brush and flush][Brush. Flush. Done]. For heavily soiled areas a pre-cleaning step is required.

*[Specifically] [Kills] [Demonstrated to kill] *Staphylococcus aureus*, Influenza AFluVirus, Rhinovirus, *Escherichia coli*, *Enterobacter aerogenes*, and *Salmonella enterica*.
†Kills Rhinovirus, which is one the three viruses that may cause cold symptoms

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[optional language]

{note to agency}

{Antibacterial/Sanitizing/Disinfecting Claims – OPTIONAL}

[Zap(s)][Zing(s)][Slams] 99.9% of [germs*][bacteria]

Anti-Bac[terial]

[Antibacterial] kitchen cleaner

Bac Attack

Beat [Bac][Bacteria][Germs*]

Bye-bye [bacteria][germs*]

Cleans as it kills [[germs*][bacteria]] [and sanitizes][and disinfects]

Cleans –or- shines –or- sanitizes-or-disinfects kitchen –and/or- household surfaces –and/or- fixtures [throughout the home –or- house]

Kill [household] bacteria [and sanitizes without bleaching]

Kill [household] germs* [and disinfects without bleaching]

Kills 99.9% of [household] bacteria [in 1 minute]

Kills [99.9%] of [bacteria] [*Staphylococcus aureus*] [*Escherichia coli*] [*Enterobacter aerogenes*]

One step cleaning and sanitizing

[Easily] [Clean[s]] –and/or- sanitize-or-disinfects [in][one easy step]

Bacteria Buster

Bacteria Jail

Bacteria Patrol

bacteria Police

bacteria Squad

bacteria Terminator

Germ* Buster

Germ* Jail

Germ* Patrol

Germ* Police

Germ* Squad

Germ* Terminator

[Kills] [eliminates] [destroys] [wipes out] 99[.9]% of [household] [germs*] [bacteria]

Tough on bacteria

Tough on germs*

Kills Influenza A [Flu] virus

Kills [a common] cold virus†

Kills Cold† & Flu Viruses

Kills viruses that cause a cold† & flu

Kills salmonella enterica

Disinfecting-or-Disinfectant-or-Sanitizing-or-Antibacterial [multi-purpose][multi-surface][all-purpose][kitchen][bathroom]cleaner

Disinfecting-or-Disinfectant-or-Sanitizing-or-Antibacterial [toilet[bowl]cleaner][Toilet Stinker Kicker][Toilet Tingle][Toilet Clean Team][Bowl Loo][Bowl Patrol][Loo [Love]

Scrub][Commode[Command][Cleanser]][Twinkle Toilet]

[optional language]
{note to agency}

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{General Claims – OPTIONAL}

[You deserve] A cleaner clean

~~[Cuts]-[Tough on] [grease]-[and/or grime] [and/or- stains]~~

[Won't harm] [Will not harm] [any] [all] [kitchen] surfaces

Hello clean

Sanitize without bleaching

Disinfect-or- kill germs* without bleaching

Kills germs* without the bleach smell

A bleach alternative

Disinfect your bathroom without the bleach smell

No harsh chemical smell

[Free of][no]dye and/or perfumes

Odorless

Made by and for the people against dirty

No harsh fumes

Psst: It's always a good idea to test in an inconspicuous place first

Won't harm kitchen surfaces

Removes soap scum

Removes hard water [stains][spots]

Soap Scum buster

A cleaner way to fight dirty

That's good karma.

The germ* extinguisher

Think of this as your [personal] germ* extinguisher

A new weapon that you can keep within reach with a [citrus-based][citric acid based]formula [and nature-inspired scents]

The [new] method [way] to fight dirty[germs] {NOTE: the term "new" will only be used for a period of 6 months from the time of agency approval}

Think of it as your [fresh-scented] micro-ninja

A kiss of death for [99.9% of] germs*

For the love of clean

Bleach-free soap scum buster

Kills germs* with citric acid

Made with citrate

[Made with] citric acid

[Made with] citric acid

Kills germs* with citrate

Kills germs* with citric acid

Method [solution] to cleaning and disinfection

Zap germs*-or-bacteria and clean up.

Packaging Claims:

100% recycled bottle

[Innovative] [cool] [Sleek] [fun] [unique] design

Recycle [for good karma]

Bottle contains [PCR][post-consumer recycled plastic].

This bottle is made [with love] from [100%][XX%] recycled plastic-or-PCR.

[optional language]
{note to agency}

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Sample Copy 1:

There's a new antibac in town and its made with a formula that's tough on grease and grime and [won't harm] [easy on] surfaces. Plus you'll be happy to know that it kills 99.9% of bacteria-or-germs*, leaving nothing behind but a fresh scent and a smile. That's a cleaner clean. [For the love of clean]

Sample Copy 2:

We're peace loving but if your mission is to [sanitize] [kill bacteria], we've got your back: anti-bac, that is. It's a [new] method that kill[s] [99.9% of] bacteria-or-germs*, all in a formula [that won't harm [any] surfaces][that's easy on surfaces][without [a] harsh smell[s]][that leaves nothing behind but a fresh scent and a smile]. BAM! Take that, [dirty][bacteria][germs].

Sample Copy 3:

There's something to that whole killing me softly thing. So we say, kill all the bacteria-or-germs you want, but do it [gently][the[method][easy] way][without harming surfaces]. Our [new] method kills [99.9% of] bacteria-or-germs* with a formula that won't harm surfaces. It still cleans like heck and smells like heaven, so now when you put the hurt on germs, you can breathe easy about it.

Bathrooms are notorious hiding places for dirt and germs.

Now you can [flush out][eliminate]the offenders[without getting caught in the crossfire].

Our [antibacterial][sanitizing][disinfecting] bathroom cleaner, [powered by][using][citrus][citric acid]. [kills 99.9% of][household][bacteria][germs*][while] shows mercy on your hard, non-porous] surfaces. It's a benevolent clean.

Bathrooms get a bad rap.

From bathroom-specific stink to the potent cleaners used to combat them, it can [feel][seem] like rather [cheerless][unwelcome] territory.

But it doesn't have to be that way.

[Now you can] eliminate dirt, germs* + the accompanying odors with our [antibacterial][disinfecting][sanitizing] bathroom cleaner [No breath-holding necessary].

Thankfully, we have you covered with a disinfecting toilet bowl cleaner that depends on [ingredients like] citric acid to eliminate bacteria and dirt.

So after a good, clean scrub, the only thing left will be the reassuring reflection of your bum coming in for landing.

You don't have to replace one unpleasant odor with another in the name of clean.

Your toilet—and your olfactory system—deserves better.

Give your bathroom a disinfecting[jolt][shock][blast] with a toilet bowl cleaner that uses [pleasantly scented] ingredients like citric acid to purge dirt and [kill] germs*-or-bacteria.

Your nose hairs will thank you.

We're getting bathroom duty off the chore blacklist with a toilet bowl cleaner that depends on citric acid to eliminate grime.

Citric acid [dissolves][destroys][kills] 99.9% of bacteria + germs* while you scrub.

[optional language]

{note to agency}

Which means that the next time you're bowing down to the porcelain gods, any gagging will be strictly due to whatever ails you, rather than a chemical plume.

All for the love of clean.

This product-or-Citric acid[dissolves][destroys][kills] 99.9% of bacteria-or-germs* while you scrub. Which means that the next time you find yourself with some time to kill while on the toilet, you can practice your yoga breathing.

Removes tough stains from you know what

Fragrance Descriptors:

go naked

[Free of][no] dye and/or perfumes

Unfragranced

citrus leaf

green melon

green fern

green leaf

watercress

laurel leaf

bamboo

ivy vine

spearmint

wildflower

[optional language]

{note to agency}

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TABLE 1

Use Sites:

<ul style="list-style-type: none"> • Countertops • Tubs • Sinks [and fixtures] • Basins • Faucets • Floors • Hand Rails • Garbage cans • Stovetops • Showers • Shower [faucets][fixtures][walls][doors] 	<ul style="list-style-type: none"> • Chairs • Diaper pails (tables) • Doorknobs • Microwave oven[s] exteriors • Oven doors • Toilet[s] [exteriors] • Toilet Bowl(s) • Toilet Seats • (whole)(entire) toilet • Under the (toilet) rim • Tubs • Urinals • Walls • Refrigerator exteriors • Stroller [Handles][Trays] 	<ul style="list-style-type: none"> • Mirrors • Bathroom surfaces • High-chairs • Kitchen Surfaces • [Kitchen] Appliance Exteriors • Ovens • Range hoods • Range tops
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Surfaces:

For use on the following hard surfaces [and prized possessions]:

Spray with confidence on the following surfaces:

Zap germs*-or-bacteria [dead][gone] on [these][the following] surfaces:

Zap germs*-or-bacteria and clean up. Suitable for most non-porous surfaces:

<ul style="list-style-type: none"> • Aluminum • Glazed ceramic [tile] • Chrome • Corian • Baked Enamel • Sealed Fiberglass • Formica 	<ul style="list-style-type: none"> • Glass • Linoleum • Hard plastic • Glazed porcelain [tile] • Stainless steel • Synthetic marble 	<ul style="list-style-type: none"> • Glazed Tile • Hard vinyl <p>Do not use on natural stone, brass, or varnished wood; for all other surfaces test in an inconspicuous area –or– spot test all other surfaces in an inconspicuous area.</p>
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TABLE 2

**[Easily] removes [the following] –or–[easily] cleans[the following]–or– use to clean
Soils:**

<ul style="list-style-type: none">• Dirt• Grime• Hard water [marks][buildup][stains]• Soap [scum –or– buildup]• [Tough] Grease• limescale• mold and mildew [stains][spots]	<ul style="list-style-type: none">• fingerprints• toothpaste• [urine-or-pee pee] stains• [fecal-or-poopy-poo poo] stains• body wash• shaving cream• shampoo• hair gel• cosmetics• lotion
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Germ-Talk

"What about my feelings?"

"Citric acid is my new nemesis."

"I don't like this one bit."

"I've officially met my match."

"I'll never understand clean."

"What have I ever done to you? Okay, beside that debilitating cold last winter."

"You think you're so smart, don't you? Well...you are, okay?. You win."

"How could you do this to me? I thought we had something special."

"Is it because of the way I smell?"

"I can change. Please, give me another chance!"

"I surrender."

"So this is how it feels to be unwanted."

"Flu season, schmu season."

"Kicking germs* and taking names, huh?"

"What's your name? I'm contagious."

"I'm not happy to report that this kills 99.9% of [household] germs*. That's bad news for me."

"Kills 99.9% of [household] germs*. Oh, great."

Selected "**Germ-Talk**"
statements (above) will
be positioned in this
dialogue box

