



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 12, 2020

Nicole Perkinson Agent Method Products Inc. 637 Commercial Street San Francisco, CA 94111

Subject: Label Amendment: Emerging Viral Pathogens Claim Product Name: FREAK EPA Registration Number: 75277-2 Application Date: March 20, 2020 Decision Number: 560989

Dear Ms. Perkinson:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-

09/documents/emerging\_viral\_pathogen\_program\_guidance\_final\_8\_19\_16\_001\_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

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- 2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
- 3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.

i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:

- A. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
- B. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
- C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (<u>www.cdc.gov/hai/outbreaks</u>)

ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page

(www.oie.int/wahis\_2/public/wahid.php/Diseaseinformation/WI).

A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.

B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE's publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

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5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rhinovirus Type 37 is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then 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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at <u>disinfectantslist@epa.gov</u>.

Sincerely,

Steven Snyderman

Steven Snyderman, Acting Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: stamped label





Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 75277-2

# Hard surface disinfectant and/or sanitizer

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

#### [CAUTION] KEEP OUT OF REACH OF CHILDREN

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Method Products Inc San Francisco, CA 94111 Questions: Phone [(xxx) xxx-xxxx] Visit: [www-xxxxxxxxxcom]

{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.

**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.

## 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*]

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

## {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<sup>+</sup> Kills Cold<sup>+</sup> & Flu Viruses Kills viruses that cause a cold<sup>+</sup> & flu Kills salmonella enterica Disinfecting-or-Disinfectant-or-Sanitizing-or-Antibacterial [multi-purpose][multi-surface][allpurpose][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]

#### {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<sup>\*</sup> 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.

May 12, 2020

### 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.

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 citron tangelo

# TABLE 1

Use Site	es:				
•	Countertops	٠	Chairs	•	Mirrors
•	Tubs	٠	Diaper pails (tables)	•	Bathroom surfaces
•	Sinks [and fixtures]	•	Doorknobs	•	High-chairs
•	Basins	•	Microwave oven[s]	•	Kitchen Surfaces
•	Faucets		exteriors	•	[Kitchen] Appliance
•	Floors	٠	Oven doors		Exteriors
•	Hand Rails	٠	Toilet[s] [exteriors]	•	Ovens
•	Garbage cans	•	Toilet Bowl(s)	•	Range hoods
•	Stovetops	٠	Toilet Seats	•	Range tops
•	Showers	٠	(whole)(entire) toilet		
•	Shower	٠	Under the (toilet) rim		
	[faucets][fixtures][walls][doors]	•	Tubs		
		٠	Urinals		
		٠	Walls		
		٠	<b>Refrigerator exteriors</b>		
		٠	Stroller		
			[Handles][Trays]		

### 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> <li>Aluminum</li> <li>Glazed ceramic [tile]</li> <li>Chrome</li> <li>Corian</li> <li>Baked Enamel</li> <li>Sealed Fiberglass</li> <li>Formica</li> </ul>	<ul> <li>Glass</li> <li>Linoleum</li> <li>Hard plastic</li> <li>Glazed porcelain [tile]</li> <li>Stainless steel</li> <li>Synthetic marble</li> </ul>	<ul> <li>Glazed Tile</li> <li>Hard vinyl</li> <li>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.</li> </ul>
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<ul> <li>Dirt</li> <li>Grime</li> <li>Hard water [marks][buildup][stains]</li> <li>Soap [scum –or- buildup]</li> <li>[Tough] Grease</li> <li>limescale</li> <li>mold and mildew [stains][spots]</li> </ul>	<ul> <li>fingerprints</li> <li>toothpaste</li> <li>[urine-or-pee pee] stains</li> <li>[fecal-or-poopy-poo poo] stains</li> <li>body wash</li> <li>shaving cream</li> <li>shampoo</li> <li>hair gel</li> <li>cosmetics</li> <li>lotion</li> </ul>
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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

#### EMERGING VIRAL PATHOGEN CLAIM

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA- Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses -Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus Type 37
Large, non-enveloped virus	Rhinovirus Type 37

Acceptable claim language:

- Freak has demonstrated effectiveness against viruses similar to [name of emerging enveloped or large, non-enveloped virus] on hard, non-porous surfaces. Therefore, Freak can be used against [name of emerging enveloped or large, non-enveloped virus] when used in accordance with the directions for use against Rhinovirus Type 37 on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.
- [Name of illness/outbreak] is caused by [name of emerging enveloped or large, non-enveloped virus]. Freak kills similar viruses and therefore can be used against [name of emerging enveloped or large, non-enveloped virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.