

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

April 21, 2020

Rebekah Baska Registration Specialist S.C. Johnson & Son, Inc. 1525 Howe Street Racine, WI 53403

Subject: Label Amendment – Emerging Viral Pathogens Claim

Product Name: Seltzer

EPA Registration Number: 4822-617 Application Date: March 11, 2020

Decision Number: 560789

Dear Ms. Baska:

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.

- 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 (www.cdc.gov/hai/outbreaks)
    - 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 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 Rotavirus 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 disinfectants list at <a href="mailto:disinfectantslist@epa.gov">disinfectantslist@epa.gov</a>.

Sincerely,

Steven Snyderman, Acting Product Manager 33

Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

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Enclosure: stamped label

## **EPA MASTER LABEL**

Seltzer

Alternate Brand Names:

Scrubbing Bubbles Bubbly Bleach Gel Toilet Bowl Disinfectant Scrubbing Bubbles Bubbly Bleach Gel Toilet Bowl Disinfectant Cleaner

## ACCEPTED

04/21/2020

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 4000 047

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#### **ACTIVE INGREDIENTS:**

Sodium Hypochlorite:	2.4%
OTHER INGREDIENTS:	97.6%
TOTAL:	00.0%

#### KEEP OUT OF REACH OF CHILDREN

DANGER: See (back) (inside) (panel for) additional precautionary statements (including first aid) (and complete use instructions) on back

Net Wt. XX

#### **DIRECTIONS FOR USE**

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

- 1. Lift the toilet seat
- 2. To remove the cap, squeeze the two side textured surfaces and unscrew completely.
- 3. (Add) (Direct) 10 ounces of liquid gel (product) under the rim and squeeze evenly around the bowl.
- 4. TO DISINFECT AND CLEAN: Allow to sit for at least 10 minutes.
- 5. Brush the entire bowl, then flush.
- 6. To close cap, turn to secure tightly until an audible click is heard.

#### STORAGE AND DISPOSAL

PESTICIDE STORAGE: Protect from freezing. Store in a cool, dry place that is inaccessible to children and pets.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available. If partially filled: Call your local solid waste agency or 1-800-529-3394 for disposal instructions.

#### PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes skin burns and irreversible eye damage. Do not get on skin, in eyes or on clothing. Wear goggles, face shield or safety glasses. Wear long-sleeved shirt and long pants, socks, shoes, and waterproof or chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using restroom. Remove and wash contaminated clothing before reuse.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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#### **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. IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. 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 or going for treatment. For additional information on this product including health concerns, medical emergencies or pesticide incidents, you may call 1-800-558-5252. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

#### PHYSICAL OR CHEMICAL HAZARDS

Combustable. Do not store near heat or open flame. Do not use or store near any oxidizing or reducing agents. Never use or mix with other household cleaners as hazardous fumes may result.

Questions? Comments? Call 800-558-5252 or Write Helen Johnson Sold by: ©[year] S.C. Johnson & Son, Inc., Racine, WI 53403-2236 U.S.A. All Rights Reserved EPA Reg. No. 4822-617 EPA Est. No. [website may be listed]

## [Optional Marketing Claims]

[Note to Reviewer: "And" or "&" can be used interchangeably in the marketing sentences. Sentences may be joined using the word "and or "or" or comma's. Exclamation marks may be used for emphasis. All claims containing the word "new" or "improved" will only be used for 6 months after the first retail production.]

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[Note to reviewer: *Type* claims may be qualified by using the *Name* from the following list:]

Туре	Name	ATCC
Bacteria	Staphylococcus aureus (Staph)	ATCC 6538
	Salmonella enterica (Salmonella)	ATCC 10708
	Pseudomonas aeruginosa (Pseudomonas)	ATCC 15442
	Enterobacter aerogenes	ATCC 13048
	Escherichia coli O157:H7 (E. coli)	ATCC 35150
	Methicillin Resistant Staphylococcus aureus (MRSA)	ATCC 33592
	Enterococcus faecalis	ATCC 29212
	Proteus mirabilis	ATCC 9240
	Shigella flexneri Serotype 1B	ATCC 9380
Viruses	Herpes Simplex Virus Type 1	ATCC VR-733
	Herpes Simplex Virus Type 2	ATCC VR-734
	Influenza A (H1N1) Virus (Influenza) (Flu)	ATCC VR-1469
	Rotavirus (Strain WA)	ATCC VR-2018
Fungi (Fungistat)	Aspergillus niger	ATCC 6275
Fungi (Fungicide)	Trichophyton interdigitale (formerly mentagrophytes)	ATCC 9533
		<u> </u>

[Note to Reviewer: Footnotes for symbols mentioned in label.]

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[Information in brackets is notes to Reviewer] (Information in parenthesis is optional language)

\*(Bacteria)(10 minute contact time for disinfection)(:) (Staphylococcus aureus (Staph) (ATCC 6538)), (Salmonella enterica (Salmonella) (ATCC 10708)), (Pseudomonas aeruginosa (Pseudomonas) (ATCC 15442)), (Enterobacter aerogenes (ATCC 13048)), (Escherichia coli 0157:H7 (E. coli) (ATCC 35150)), (Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33592)), (Enterococcus faecalis (ATCC 29212)), (Proteus mirabilis (ATCC 9240), (Shigella flexneri Serotype 1B (ATCC 9380))

^(Viruses)(10 minute contact time for disinfection)(:) Herpes Simplex Virus Type 1 (VR-733), Herpes Simplex Virus Type 2 (VR-734), Influenza A (H1N1) Virus (Influenza) (Flu) (VR-1469), Rotavirus (Strain WA) (R-2018)

<sup>‡</sup> (Germs)(10 minute contact time for disinfection)(:) *Staphylococcus aureus* (Staph) (ATCC 6538), *Salmonella enterica* (Salmonella) (ATCC 10708), *Pseudomonas aeruginosa* (Pseudomonas) (ATCC 15442), *Enterobacter aerogenes* (ATCC 13048), *Escherichia coli* 0157:H7 (E. coli) (ATCC 35150), Methicillin Resistant *Staphylococcus aureus* (MRSA) (ATCC 33592), Herpes Simplex Virus Type 1 (VR-733), Herpes Simplex Virus Type 2 (VR-734), Influenza A (H1N1) Virus (Influenza) (Flu) (VR-1469), Respiratory Syncytial Virus (RSV) (VR-26), Rotavirus (Strain WA)

(∞)(Fungi)(:) (Trichophyton interdigitale) (ATCC 9533), (Aspergillus niger) (ATCC 6275)

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{Note to Reviewer: These statements for claims against large, non-enveloped viruses, shall not appear on marketed (final print) labels.}

## **EMERGING VIRAL PATHOGENS**

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

For an emerging viral pathogen that is	follow the direction for use for the	
a/an	following organism on the label	
Enveloped virus	Rotavirus	

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard non-porous surfaces. Therefore, [Product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Rotavirus 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 virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the direction for use against Rotavirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

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## Disinfecting claims:

- Antibacterial\* (Disinfecting) (Action) formula
- Antimicrobial (Bactericidal) (Bactericide) (Disinfectant) (Disinfects) (Germicidal<sup>‡</sup>) (Virucidal<sup>^</sup>) (Fungicidal<sup>∞</sup>)
- Bacteria-fighting\* (germ-fighting<sup>‡</sup>) (Virus-fighting<sup>^</sup>) Formula
- Cleans (Brightens) (Deodorizes) (Disinfects) with bleach
- Destroys (Powers Through) (Removes) (Eliminates) mold stains (and) (&) mildew stains
- Disinfects (Deodorizes) (against odor-causing) (bacteria\*) (germs<sup>‡</sup>)
- Get (Make) your toilet clean with Scrubbing Bubbles® Bubbly Bleach Gel Toilet Bowl (Cleaner) (Disinfectant), and keep it fresh (clean) with Scrubbing Bubbles® Toilet (Cleaning) (Fresh) Fresh Gel (Stamp)
- Helps Prevent (Controls) (Inhibits) Mold & Mildew
- Kills 99.9% of bacteria\*, virus<sup>^</sup> and mold fungi<sup>®</sup>
- A bleach product for toilet cleaning and disinfecting
- Bleach disinfects and whitens your toilet bowl
- Bleach Toilet Disinfectant (Cleaner)
- Brightens as it cleans (disinfects)
- Cleans (disinfects) above and below the waterline
- Cleans as it disinfects
- Disinfecting Bleach
- Disinfects (cleans) toilet (bowl) surfaces
- Disinfects (cleans) your toilet (bowl)
- Disinfects against (Kills) toilet bacteria\* (germs<sup>‡</sup>)
- Disinfects and deodorizes by killing (toilet) germs<sup>‡</sup> and controlling their odors
- Disinfects and deodorizes by killing bathroom germs<sup>‡</sup>
- Disinfects in hard to reach areas (like) (under the rim) (into the 'S' bend)
- Disinfects toilets (bidets) (urinals)
- Disinfects under the rim
- Easily and effectively disinfects toilet bowls (urinals)
- Great for everyday cleaning (deodorizing) (disinfecting) (Home) disinfectant toilet bowl cleaner
- Kills (99.9% of) viruses and bacteria\*
- Kills (the) most germs<sup>‡</sup>
- Kills bacteria\*
- Kills germs<sup>‡</sup>
- Kills 99.9% of (household) bacteria\* (germs<sup>‡</sup>) (with bleach)
- Kills 99.9% of bacteria\*, virus<sup>^</sup> and mold fungi<sup>^</sup>
- Kills Mold & Mildew
- Kills (odor-causing) bacteria\*
- Kills the bacteria\* that cause bad odors
- Leaves toilet sparkling clean and disinfected
- Reaches hidden germs<sup>‡</sup> and grime under the rim
- Removes Odors by killing odor-causing bacteria\*

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## **Cleaning Claims:**

- Deodorizes and has (leaves) a clean (fresh) scent (fragrance)
- (Has the) (Cleaning) Power of Bleach
- Keeps (Leaves) the (your) toilet (bowl) bleach-clean
- (Manual) (Bleach) Toilet Bowl Cleaner
- (The new) Scrubbing Bubbles Foaming Bleach Gel Toilet (Bowl) Cleaner combines the power of bleach and the cleaning action of foaming bubbles in just one product
- Active Foam (Bubbles) (Cleans) (Freshens)
- An effective cleaner for use in the toilet
- Basic Bleach meets hardworking bubbles
- Brightens (Whitens) (as it cleans) (your Bowl)
- Brightens (whitens) and removes (dirt) stains
- Cleaning Foam (Bubbles)
- Cleans (deodorizes) (and freshens) (your toilet bowl) (with the power of bleach)
- Cleans and deodorizes the toilet bowl
- Contains (a powerful) cleaner(s) (plus bleach)
- Designed to clean under the rim
- Effectiveness of bleach with a clean, fresh scent
- Foams and Freshens
- For a (super) (thoroughly) clean (bright) (shiny) (white) toilet bowl (surface)
- For a hardworking bleach clean
- Freshens (toilet bowl)
- Hard working bubbles lift away dirt and grime as you brush
- Helps keep the (your) toilet (bowl) fresh and clean
- Leaves the (your) Toilet (bowl) (sparkling) clean (sanitary)
- Leaves a sanitary clean and fresh toilet
- Make (Get) it Clean, keep it Fresh (Clean)
- Specially designed neck makes it easy to clean under the rim
- The power of bleach (+) (plus) foam smells like (a Rainshower) (Citrus) (Lavender)
- Whitening Bleach
- Whitens (with the power of bleach)
- You can get it clean with (New) (Scrubbing Bubbles®) Bubbly Bleach, and keep it fresh with (Scrubbing Bubbles®
  (Toilet) (Fresh) Gel

## **Miscellaneous Marketing claims:**

- Easy (Extended) Reach Neck (for) (Under the Rim)
- We work hard so you don't have to (TM or ®)
- See the Foam. Smell the Difference
- Complete (full) (total) toilet bowl coverage
- Easy to use
- Fresh (Lavender) (Rainshower) (Tropical Sunshine) ) (Citrus) Scent
- Floral Fusion
- Tropical Sunshine
- Fierce Fresh
- (Dazzling Petals)

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- Lavender
- Citrus
- Rainshower
- Pleasant Fragrance
- Thick (Gel) Formula
- Will not harm (safe for) plumbing or septic systems
- Coats the entire bowl
- (Easy to) (Easily) reach under the rim
- Value (bonus) Pack
- Twin (2) Pack
- Triple (3) Pack
- X Uses (per) (pack) (bottle)
- S.C. Johnson (& Son) (A Family Company) (At Work for a Better World) (Wax)(since 1886) (Fisk Johnson [signature])
- Peel (remove) (tear) label (sticker) (coupon) (here) for complete use directions
- Peel (remove) (tear) label (sticker) (coupon) (here) for complete use directions and precautionary statements
- Peel (remove) (tear) label (sticker) (coupon) (here) before use

## **Graphics**



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[Information in brackets is notes to Reviewer] (Information in parenthesis is optional language)







