



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 6, 2020

Joey Liu
VP of Regulatory Affairs
Legal
Melaleuca Inc.
4609 West 65th South
Idaho Falls, ID 83402

Subject: Label Amendment – Emerging Viral Pathogens Claim
Product Name: SBT 2 to 1 Concentrate
EPA Registration Number: 66251-2
Application Date: March 16, 2020
Decision Number: 560817

Dear Joey:

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.

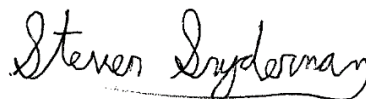
2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be 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 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.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Poliovirus Type 1 and 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 disinfectants list at disinfectantslist@epa.gov.

Sincerely,



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

Enclosure: stamped label

{MASTER LABEL}

{All text in brackets [xxx] is optional and may or may not be included on a printed label.}

{All text in braces {xxx} is administrative and will not appear on a printed label.}

Primary Brand Name: SBT 2 to 1 Concentrate; ABN: Sol-U-Guard Botanical 2x Concentrate Disinfectant

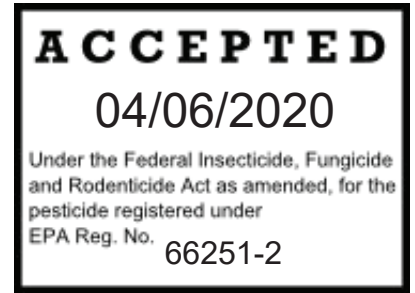
{Concentrate label}

{Front Panel}



Sol-U-Guard Botanical 2x Concentrate Disinfectant

Kills 99.9% of bacteria and viruses* on hard, nonporous surfaces.



ACTIVE INGREDIENTS:

Citric Acid.....	4.00%
Thymol (present as a component of Thyme Oil).....	0.092%
OTHER INGREDIENTS:.....	95.908%
Total.....	100.000%

U.S. Patent No. 7,642,227

U.S. Patent No. 7,851,430

CAUTION: Keep out of reach of children.

See back panel for additional Precautionary statements.

XX FL OZ (XXX mL)

{Back Label}

Sol-U-Guard Botanical 2x Concentrate Disinfectant formula combines thyme oil and citric acid. It is proven to kill 99.9% of bacteria and viruses* on hard, nonporous surfaces. Your whole family can breathe easier knowing that the germ*-killing power of thyme oil not only makes an effective disinfectant, but it also infuses your home with the pleasant scent of the herb thyme.

Sol-U-Guard Botanical 2x Concentrate Disinfectant contains no bleach or phosphates, creates no harsh fumes, and leaves no harmful residue.

*Kills 99.999% of *Escherichia coli* (E. coli), and *Staphylococcus aureus* (staph) in 1 minute. Kills 99.9% of *Enterobacter aerogenes* in 30 seconds. Disinfects against *Salmonella enterica* (salmonella), *Pseudomonas aeruginosa*, *Streptococcus pyogenes* (strep), Methicillin Resistant *Staphylococcus aureus* (MRSA), Influenza A virus, Poliovirus type 1, Rhinovirus type 37, and Rotavirus in 10 minutes. Disinfects against Influenza A virus (Swine/Iowa/15/30) in 1 minute.

For use in homes, on faucets, sinks, drains, doorknobs, telephones, external surfaces of microwaves, external surfaces of refrigerators, appliances, countertops, light switches, tables, toilet seats, pet habitats, pet bowls, litter boxes, garbage cans, children's toys†, high chairs, changing tables, computer

keyboards & mice, prostheses & orthotics, sports equipment such as jock cups and helmets, and any other nonporous surface where bacteria, viruses, or unpleasant odors are a concern.

Do not use on natural marble or stone.

Do not mix with an active chlorine source such as household bleach or sodium hypochlorite. Do not mix with strong base such as lye or sodium hydroxide.

†Rinse children's toys and jock cups with potable water.

Manufactured by:

Melaleuca, Inc.,

4609 West 65th South

Idaho Falls, ID 83402

To order: 1-800-282-3000

www.melaleuca.com

Product of USA #4020 XX/XXU

EPA Reg. No. 66251-2

EPA Est. No. 66251-ID-003 or EPA Est. No. 66251-ID-001 or EPA Est. No.: 66251-TN-001

Kosher symbol.

100% SATISFACTION GUARANTEE symbol.

{Bottom of bottle or imprinted on label}

Batch code

{Peel Back Label}

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

TO DILUTE: Pour *Sol-U-Guard Botanical 2x Concentrate Disinfectant* concentrate into mixing spray bottle {(#8901) or other spray bottle number} to line and fill with water or add XX fl. oz. concentrate to XX fl. oz. water {the fl. oz. using 1:1 ratio to be determined depending upon volume of spray bottle}. Avoid splashing.

TO CLEAN: Spray diluted product on area to be cleaned until thoroughly wet and wipe or rinse away.

TO SANITIZE: Spray diluted product on surface until thoroughly wet. Let stand 1 minute. Wipe and let air dry. No rinsing is necessary.†

TO DISINFECT: Preclean surface to remove soil before disinfection. Spray diluted product on surface until thoroughly wet. Let stand 10 minutes before wiping. No rinsing is necessary.†

TO DEODORIZE: Spray on surface as needed.

STORAGE AND DISPOSAL

Storage: Store in a cool, dry place. Disposal: Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

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

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue to rinse 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 or going for treatment. To contact a regional poison control center call 1-800-222-1222.

<<Emerging Viral Pathogens Claim – Hard, non-porous surfaces>>

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.

(Note to the reviewer: The statements shall be made only through the following communications outlets: technical literature distributed exclusively to veterinarians, 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.)

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...	...following the directions for use for the following organisms on the label:
Enveloped virus	Rhinovirus type 37 Poliovirus type 1
Large, non-enveloped virus	Rhinovirus type 37 Poliovirus type 1

(Product name -or- this product) has demonstrated effectiveness against viruses similar to **(name of emerging virus)** on hard, **(porous and/or non-porous surfaces)**. Therefore, **(product name -or- this product)** can be used against **(name of emerging virus)** when used in accordance with the directions for use against **(name of supporting virus(es))** on **(hard, porous/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 -or- this product)** kills similar viruses and therefore can be used against **(name of emerging virus)** when used in accordance with the directions for use against **(name of supporting virus(es))** on **(hard, porous/non-porous surfaces)**. Refer to the **(CDC or OIE)** website at **(website address)** for additional information.