

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

September 27, 2024

E. David Lewis Agent for Melaleuca, Inc. 2461 South Clark Street Arlington, VA 22202

Electronic Transmittal: <u>dlewis@lewisharrison.com</u>

Subject: PRIA Label and CSF Amendment – CSF Amendment, Adding Efficacy Claims for

SARs, and Suppliers of a Commodity Chemical

Product Name: SBT 2 to 1 Concentrate EPA Registration Number: 66251-2

Received Date: 09/29/2022 Action Case Number: 00396932

Dear David Lewis:

The amended label and CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are 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. Pursuant to 40 CFR 156.10(a)(6), 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.

Please note that the record for this product currently contains the following CSF: (Please note the proposed alternate CSF 1 has been replaced by the Basic CSF).

Basic CSF dated September 29, 2022

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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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.

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, please contact Terria Northern via email at northern.terria@epa.gov

Sincerely,

Marcel Howard, Product Manager 34 Regulatory Management Branch II Antimicrobials Division (7510M) Office of Pesticide Programs

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Enclosure: Approved 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 on hard, nonporous surface*. Disinfects 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)

ACCEPTED

66251-2

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 09/27/2024

{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 on hard, nonporous surfaces* and disinfects bacteria and viruses on hard, nonporous surfaces[‡]. This effective disinfectant also infuses your home with the pleasant scent of the herb thyme.

Sol-U-Guard Botanical 2x Concentrate Disinfectant contains no bleach or phosphates.

*Kills 99.9% of Staphylococcus aureus (Staph) and Klebsiella aerogenes in 30 seconds.

†Disinfects against Staphylococcus aureus (Staph), 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 [(H3N2)] [(H3N2: A/Hongkong/8/68)] in 1 minute. Disinfects against SARS-CoV-2 [(COVID-19 Virus)] [(USA-WA1/2020)] [(cause of COVID-19)] in 30 seconds.

For use in homes, on faucets, sinks, doorknobs, telephones, external surfaces of microwaves, external surfaces of refrigerators, appliances, light switches, tables, toilet seats, pet habitats, litter boxes, garbage cans, high chairs, changing tables, computer keyboards & mice, prostheses & orthotics, sports equipment such as jock cups and helmets, and any other hard, non-porous and non-food contact 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.

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 hard, non-porous and non-food contact surface until visibly wet. Let stand 1 minute. Wipe and let air dry. No rinsing is necessary.

TO DISINFECT: Preclean surfaces to remove soil before disinfection. Spray diluted product on hard, non-porous and non-food contact surface until visibly wet. Allow surface to remain visibly wet for 10 minutes before wiping. No rinsing is necessary.

TO DEODORIZE: Spray on surface as needed.

STORAGE AND DISPOSAL

{Note to Reviewer: The following statements are for nonrefillable container (residential use) 1 gallon or less.}

Storage: Store in a cool, dry area.

Pesticide Disposal: Discard in trash or offer for recycling if available.

Container Handling: Nonrefillable container. Do not reuse or refill empty container.

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 gun, 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, 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, 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, non-porous surfaces. Refer to the (CDC or OIE) website at (website address) for additional information.