

66251-2

03/14/2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

MAR 14 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Herbert Estreicher
Agent for Malaleuca, Inc
Keller and Heckman, LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Subject: SBT 2 to 1 Concentrate
EPA Registration No.: 66251-2
Amendment Date: , 2010
EPA Receipt Date:, 2010

Dear Mr. Esteicher,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with conditions.

Proposed Amendment

Add additional claims against Rotavirus, Swine Influenza A, and MRSA

Conditions

Revise the label as follows:

- 1.) Delete the claim, Gentle enough to use around kids, pets, and food, because it is an implied safety claim according to 40 CFR Part 156.10(a)(5).
- 2.) AOAC has changed the nomenclature for *Salmonella choleraesuis* to *Salmonella enterica*. Revise your label accordingly.
- 3.) Revise the claim, "Safe for use on..." to read "Will not harm..."

Data Summary

	Data Requirement	Means of Support	Status
	Virucidal Efficacy against Rotavirus	Submitted study, MRID 481211-01	Acceptable, RTU in 10 min
	Virucidal Efficacy against Swine Influenza A (H1N1) Virus	Submitted study, MRID 481211-02	Acceptable, RTU in 10 min
SYMBOL	AOAC Germicidal Spray Method- MRSA	Submitted study, MRID 481211-03	Acceptable, RTU in 10 min
SURNAME			
DATE			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

General Comments

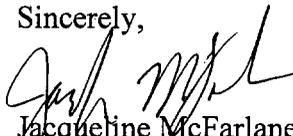
A stamped accepted label is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have further questions concerning this letter, please contact me at 703-308-6416 or by email at Campbell-mcfarlane.jacqueline@epa.gov or Killian Swift at (703) 308-6346 or by email at swift.killian@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,



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

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

{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.

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAR 14 2011

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

66251-2

ACTIVE INGREDIENTS:

Citric Acid.....4.00%
Thymol (present as a component of Thyme Oil).....0.092%

OTHER INGREDIENTS:.....95.908%
Total.....100.000%

Keep Out of Reach of Children
CAUTION
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. ~~Gentle enough to use around kids, pets, and food.~~

*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 choleraesuis* (salmonella), *Pseudomonas aeruginosa*, *Streptococcus pyogenes* (strep), Methicillin-Resistant *Staphylococcus aureus* (MRSA), Influenza A, 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 & helmets, and any other nonporous surface where bacteria, viruses, or unpleasant odors are a concern.



Kosher symbol.

100% SATISFACTION GUARANTEE symbol.

Manufactured by:
Melaleuca, Inc.,
3910 S. Yellowstone Hwy
Idaho Falls, ID 83402-6003
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
Batch code

~~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.

[Safe for use on acrylic, glazed ceramic, chrome, sealed fiberglass, glass, vinyl, laminated and synthetic surfaces.]

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 bases such as lye or sodium hydroxide.

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

STORAGE AND DISPOSAL

Storage: Store in a cool, dry place.

Container Disposal:

{Concentrate container} Nonrefillable container. Do not reuse or refill this container. 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.

