



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

December 6, 2024

Jonathan Walsh
Agent for Sterisil, Inc.
Technology Sciences Group Inc.
1150 18th St. NW, Suite 1000
Washington, DC 20036
Electronic Transmittal: Jonathan.Walsh@tsgconsulting.com

Subject: Label and CSF Amendment – Update the first aid statement, Storage and Disposal, and the Directions for Use; and add alphabetize Optional Marketing Language in the label. Also, CSF Amendment to update the suppliers on basic, alternate 1 and alternate 2 CSFs.
Product Name: Citrisil
EPA Registration Number: 83315-1
Received Date: 7/19/2021
Action Case Number: 00311852

Dear Jonathan Walsh:

The amended label and CSF(s) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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.

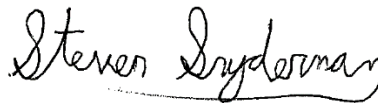
Please note that the record for this product currently contains the following CSF(s):

- Basic CSF dated 10/1/2024
- Alternate CSF 1 dated 10/1/2024
- Alternate CSF 2 dated 10/1/2024

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 Srinivas Gowda by phone at 202-565-0078 or via email at gowda.srinivas@epa.gov

Sincerely,



Steven Snyderman, Product Manager 33
Regulatory Management Branch II
Antimicrobials Division (7510M)
Office of Pesticide Programs

Enclosures:

AD Product Chemistry Review_Citrisil_EPA Reg. No. 83315-1_Action Code: 00311852.

Citrisil™

[All in One] Dental Waterline [Microbial¹ Contaminant Control] [Antimicrobial¹] Tablet

Citrisil™ is specially formulated and clinically proven to:

- Kill odor causing bacteria
- Maintain dental unit water line effluent [less than or equal to] [\leq] 10 CFU/ml
- Clean dental unit waterlines
- [Maintain silver ion based antimicrobial tubing]

Citrisil is formulated to be continuously present in the dental [unit] water system. This product is not for use against public health organisms.

{Note to Reviewer: the following sentence may be printed in standard capitalization}
PLEASE SAVE [THESE/THE] DIRECTIONS FOR FUTURE USE.

KEEP OUT OF REACH OF CHILDREN
CAUTION

Active Ingredient
Silver..... 0.78%
Other Ingredients:99.22%
Total:100.00%

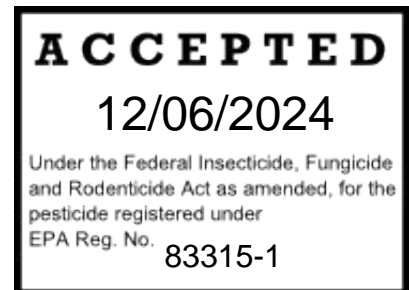
Net Contents/Weight (Part No.) (Net Weight.) (tablet count) (2 shock tablets and 48 maintenance tablets) (1 shock tablet, 12 white tablets [&/and] 12 blue [maintenance] tablets) (20 shock tablets) (2 shock tablets) (4 shock tablets)

EPA Reg. No. 83315-1
EPA Est. No.
Patent No. 6,991,736

Manufactured [by/for]
Sterisil, Inc.
835 S. Hwy. 105, Unit D
Palmer Lake, CO 80133
+ 1 719 622 7200 or online at Sterisil.com
[Sterisil.com] [Company email address] [phone] [number]
[visit [us online at] (company website)]

[Company Logo]

[See insert for directions for use .]



FIRST AID

If in Eyes	Hold eye open and rinse slowly and gently with water 15 to 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
If on Skin	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.
[For information such as copy of Safety Data Sheet, call Sterisil Inc. at +1 719 622 7200 Monday through Friday, 8:00 AM to 4:00 PM Mountain Standard Time.]	
For information on this pesticide product (including general health concerns or pesticide incidents), call the [National Pesticide Information Center] at [1-800-858-7378], [Monday through Friday, 8:00 AM to 12:00 PM] [Pacific Standard Time]. In the event of a medical emergency, call your poison control center at [1-800-222-1222].	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye and skin irritation. Avoid contact with eyes, skin, and clothing. Avoid touching tablet with bare skin. Wear gloves and goggles/ safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates.

PHYSICAL OR CHEMICAL HAZARDS

The product will react with strong acids or oxidizing agents. Do not use with or store near any oxidizing or reducing agents. Premature exposure to moisture may reduce tablet effervescent ability. Exposure to direct light may cause tablet to change color.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store in a cool dry place at room temperature and out of direct sunlight.

PESTICIDE DISPOSAL

Empty container by using product according to label directions.

CONTAINER HANDLING

Nonrefillable container. Do not re-use or refill this container. Dispose of empty pouch and container in the trash or offer for recycling if available

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[NOTE:]This product is for use with potable water. If condition of water is unknown, a water sample should be sent to third-party labs for testing before use. For optimum performance follow the directions.

Citrisil is for use as an antimicrobial¹ on [dental] [unit] waterlines. When used according to the label, optimum control of odor causing bacteria can be achieved.

Citrisil tablets are available in multiple sizes and colors in order to provide protection for various [dental] waterline configurations. The (orange OR other color) shock tablet should be used first and, thereafter, monthly. Citrisil is available for bottles containing up to one liter of water and for bottles containing up to two liters of water. [For bottles larger than two liters, contact Sterisil directly.] Both sizes of maintenance tablets come in a clear version and a version with a blue dye that provides a visual treatment compliance aid.

{Note to reviewer: Depending upon the tablet(s) selected, one or more of the following sections will be used.}

[To use a shock tablet:

1. Empty water from bottle.
2. Drop (orange OR other color) shock tablet into bottle. Do not touch tablet with unprotected skin.
3. Add 177 ml. (6 fl. oz.) of warm **distilled water**.
4. Wait at least 60 seconds for tablet to fully dissolve.
5. Swirl (orange OR other color) shock solution to clean and treat the inside of the bottle.
6. Connect bottle to dental unit and run all lines until (orange OR other color) color appears.
7. Leave in all lines overnight.
8. The following day empty (orange OR other color) shock solution from bottle.
9. Purge until the (orange OR other color) color dissipates and treat with Sterisil's maintenance product or an antimicrobial that is EPA registered for dental waterline use.

Upon initial use of the shock tablet, it may be necessary to repeat steps 1 through 7 additional times to eradicate remaining odor causing bacteria or any residual chemicals from other treatment products.]

[To maintain a bottle up to one liter in size:

1. Either a blue or white 90 mg tablet may be used.
2. Add 1 tablet into an empty 0.7 liter (24 fl. oz.) or 1 liter (34 fl. oz) water bottle by dropping the tablet directly into the bottle. Do not touch tablet with unprotected skin.
3. Fill bottle with distilled quality water or tap* water, wait at least 60 seconds for tablet to dissolve, connect bottle to dental unit.
4. If just completing shock treatment, purge waterlines until orange color dissipates.
5. Initiate patient care.
6. When bottle is empty, repeat these maintenance treatment steps.]

[To maintain a bottle greater than one liter to two liters in size:

1. Either a blue or white 180 mg tablet may be used.
2. Add 1 tablet into an empty 1.5 liter (51 fl. oz.) or 2 liter (68 fl. oz.) water bottle by dropping the tablet directly into the bottle. (add two 1 liter tablets for 2 liter (68 fl. oz.) bottles). Do not touch tablet with unprotected skin.
3. Fill bottle with distilled or purified tap* water, wait at least 60 seconds for tablet(s) to dissolve, connect bottle to [dental] unit.
4. If just completing a shock treatment, purge waterlines until orange color dissipates.
5. Initiate patient care.
6. When bottle is empty, repeat these maintenance treatment steps.]

*Distilled quality water is recommended, however if using tap water, Sterisil recommends to rinse and empty bottle once per week to remove any tap water impurities that may have settled out.

Citrisil may be left in the waterlines overnight and for extended periods of non-use, up to two weeks. It is not necessary to purge lines at the end of each day.

NOTE: It is recommended to test output water bacteria¹ levels monthly until passing and then quarterly thereafter. Laboratory monitoring of bacteria¹ levels can verify that water treatment protocols are being performed correctly and are effective. Contact Sterisil for assistance with in-office or independent third-party water testing.

{Note to reviewer: Only the appropriate section of this chart will appear on the label based on the tablet selected. 'Net Contents' and 'Use' columns may or may not appear on the label.}

[Citrisil] Part No.	Net Contents	Use	Formulation
C50-W	2 shock tablets and 48 maintenance tablets	Maintenance and shock	1LW, ECS
C50-2W	2 shock tablets and 48 maintenance tablets	Maintenance and shock	2LW, ECS
C50-B	2 shock tablets and 48 maintenance tablets	Maintenance and shock	1LB, ECS
C50-2B	2 shock tablets and 48 maintenance tablets	Maintenance and shock	2LB, ECS
C25-Trial	12 white and 12 blue maintenance tablets and 1 shock tablet	Maintenance and shock	1LW, 1LB, ECS
ECS-20	20 shock tablets	Shock treatment	ECS
ECS-4	4 Shock Tablets	Shock treatment	ECS

Optional Marketing Language {may appear on any label}

- All-in-one
- All-in-one tablet
- All-in-one tablet, shock and daily maintenance dental waterline tablet.
- Citrisil™ Waterline Maintenance Tablets.
- Continuously treats and maintains dental water lines.
- Does not dissolve amalgam.
- Controls odor-causing bacteria in dental unit water lines.
- [Controls] [Reduces] [Inhibits] odor-causing bacterial contamination in [dental unit water lines] [effluent water]
- Does not adversely affect composite bond strength.
- For the Cleaning and Control of Microbial Contamination in Dental Unit Waterlines.
- It is not necessary to purge lines at the end of each day.
- Made in USA.
- Suitable for patients and clinicians.
- Shock included.
- [This product] is specially formulated and proven to control contamination in dental unit water lines by reducing and inhibiting the re-growth of odor-causing bacteria.

- Treats dental unit waterlines
- Will not harm dental equipment
- May need to perform additional shock treatments using shock tablets to lower odor-causing bacteria count (CFU/mL)
- Odor free
- Waterline responsibility [one tablet at a time]
- Easy to implement
- Your complete dental waterline solution¹
- Complete waterline treatment solution¹
- Shock included
- Tested for compatibility with [critical handpiece components] [common handpiece components] [common handpiece materials]
- Antimicrobial¹ cleaner
- Cleans and maintains [dental] unit waterlines
- Dental [unit] waterline tablet
- Visit us online at Sterisil.com

Optional quick identifier for label

- [Maintenance [size/box]] [50 tablets] [shock included]
- [Starter [size/box]] [Trial [size/box]] [25 tablets] [shock included]
- [Shock [size/box]] [20] [4] [2] tablets [shock included]

Endnotes:

- 1- Controls the growth of odor-causing bacteria
- 2- Dental amalgam separators and removal devices are not compatible with specified chemistries.

ISO 13485 approved address and symbols

[EU Authorized Representative following UK and EU Requirements]

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

