



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 7, 2021

Julie Ownbesy  
Regulatory Consultant  
Sterisil, Inc.  
835 S. Hwy 105, Suite D  
Palmer Lake, CO 80133

Subject: Label and CSF Amendment – Silver Reclassification Response to GDCI  
Product Name: Sterisil Dental Water Microbiological Cartridge  
EPA Registration Number: 83315-2  
Received Date: January 7, 2020  
Action Case Number: 00220360

Dear Julie:

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):

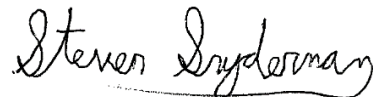
- Basic CSF dated 10/12/2020
- Alternate CSF 1 dated 10/12/2020
- Alternate CSF 2 dated 10/12/2020
- Alternate CSF 3 dated 10/12/2020

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 Perri Moeller by phone at (703) 347-8618, or via email at [moeller.perri@epa.gov](mailto:moeller.perri@epa.gov).

Sincerely,

A handwritten signature in black ink that reads "Steven Snyderman". The signature is written in a cursive style with a horizontal line underneath the name.

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

Enclosure: Stamped Label

{Note to Reviewer: Language in [brackets] is optional.}



## Sterisil Dental Water Microbiological Cartridge

Sterisil Dental Water Microbiological Cartridges are formulated and clinically proven to kill odor causing bacteria, maintain dental unit waterline effluent [less than or equal to]  $\leq$  10 CFU/ml, [and] clean dental unit waterlines[.] [and maintain silver ion based antimicrobial tubing.] Treated water should be continuously present in the [dental][unit] water system.

**PLEASE SAVE [THESE/THE] DIRECTIONS FOR FUTURE USE.**

KEEP OUT OF REACH OF CHILDREN

### CAUTION

Active Ingredient:  
Silver ion\* 17.5%  
Other Ingredients: 82.5%  
Total: 100.0%

*\*bound to hydrogen form weak acid gelular cation exchange resin*

**Net Contents:** 1 Dental Water Microbiological Cartridge [1 cartridge] [1 unit] – (Part No.) (Net Weight.)

**EPA Reg. No.** 83315-2

**EPA Est. No.**

Patent No 6 991 736

**Manufactured [by/for]**

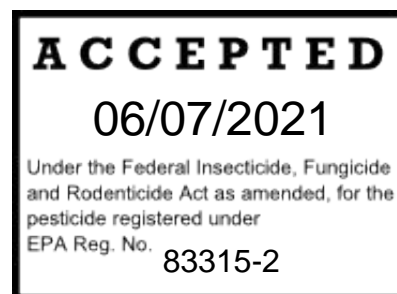
Sterisil Inc.

835 S Hwy 105 Suite 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)]

[See insert for directions for use, [precautionary [language]], [[warranty] statement], [first aid statements], and [storage and disposal].]

FIRST AID	
<b>If in Eyes</b>	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.
<b>If on Skin</b>	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.

*Sterisil Dental Water Microbiological Cartridge (83315-2)*

Sterisil, Inc.

Amendment – December 19, 2019, Label Version (3) June 22, 2020

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{Note to Reviewer: Language in [brackets] is optional.}

## **PRECAUTIONARY STATEMENTS**

### **HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

### **ENVIRONMENTAL HAZARDS**

Silver is toxic to fish and aquatic invertebrates.

### **STORAGE AND DISPOSAL**

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

#### **PESTICIDE STORAGE**

Store in a cool dry area out of direct sunlight.

#### **PESTICIDE DISPOSAL**

Discard in trash or offer for recycling if available. [Sterisil offers a recycling program for the antimicrobial resin and encourages users to take part in Sterisil's volunteer efforts towards a greener tomorrow.]

#### **CONTAINER HANDLING**

Nonrefillable container. Do not reuse this container. Dispose of empty packaging in trash. If cartridge breaks, place debris into a sealed plastic bag and discard in trash.

## **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 intended for use with potable water. Do not use softened water with this product. For optimum water flow, 40 PSI is recommended.

Sterisil Dental Water Microbiological Cartridge is for use as an antimicrobial on [dental] [unit] waterlines. When used according to the label, optimum control of odor causing bacteria can be achieved.

Sterisil Dental Water Microbiological Cartridge is available in multiple [model/class/size] types in order to provide [protection] [treatment] for various [dental] waterline configurations. The straw model type is for use in [dental] bottles, [the cartridge/direct feed/municipal] model type is for directly fed [dental] units and the [system/Stage 5] model type is used in conjunction with a Sterisil System]. Each [model/class/size] type comes in a variety of sizes to fit multiple office sizes, water types and [dental] unit setups.

### **[INITIATING] SHOCK TREATMENT**

**[All models:]** Sterisil Dental Water Microbiological Cartridge is engineered to automatically produce a "shock" treatment after initial connection. Run all lines attached to the dental units into a white cup until blue tinted water appears exiting each line. Run no more than 6oz (3/4 cup) of water during this process. Allow all lines to remain unused for a minimum of 8 hours. For best results, allow shock to

{Note to Reviewer: Language in [brackets] is optional.}

remain in the line(s) over the weekend. **Prior to use of [dental] unit, flush [dental] lines until blue tint disappears (approximately 4 ounces).**

{Note to reviewer: Depending upon the model type, one of the three sections below will be used: Straw Model, [Cartridge/direct feed] Model, or [System/Stage 5] Model.}

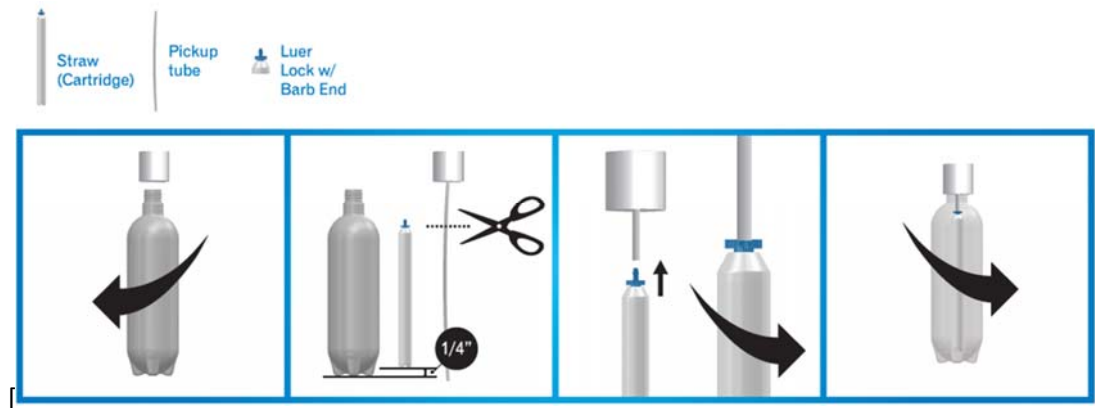
### **{STRAW MODEL LANGUAGE}**

#### **To [maintain] [install] bottle use configuration [use the straw model]**

1. Remove the [dental] bottle from the manifold.
2. Cut the [dental] unit's existing pickup tube and install the straw. Be sure to allow for at least a ¼" gap between the end of the straw and the bottom of the bottle.
3. Insert the luer lock [(located on the straw)] into the cut end of the pickup tube.
4. Ensure the straw is screwed tightly onto the luer lock.

[For replacement: Twist off the straw while keeping the pickup tube and luer lock in place. Twist on a new straw.]

[Visit Sterisil.com to watch the installation video]



[Colors in graphic may vary]

### **MAINTENANCE TREATMENT**

#### **[Straw Models:]**

Fill independent water bottle with distilled water, distilled quality water or good quality municipal water.\* The [dental] water is automatically treated as it runs through the straw. Replace the straw [product] per the cartridge capacity & replacement schedule.

\*STRAW PERFORMANCE REQUIREMENTS: Source water for the [S90/S365] [part number(s) \_\_] should read 100 ppm or less on a Total Dissolved Solids (TDS) meter. Source water for [S90m/ S365m] [part number(s) \_\_] should read greater than 100 ppm, but no more than 250 ppm, on a TDS meter. If source water is greater than 250 ppm on a TDS meter, use distilled water or distilled quality water with a distilled straw.

It is recommended that you use [a Sterisil® Antimicrobial Bottle] [an antimicrobial bottle] [alternate brand name: BioFree® Bottle] and [clean] [treat] [shock] your bottle quarterly with a Citrisil™ shock tablet to maintain the antimicrobial efficacy. If you have not purchased [a Sterisil Antimicrobial Bottle] [an antimicrobial bottle] [alternate brand name: BioFree® Bottle] we recommend you [clean] [treat]

{Note to Reviewer: Language in [brackets] is optional.}

[shock] your bottles more frequently with a Citrisil™ shock tablet to inhibit the growth of any microorganisms that may be present.

{Note to Reviewer: Language in [brackets] is optional.}

**[[CARTRIDGE/DIRECT FEED] MODEL LANGUAGE]**

**[Two versions available: Inline [cartridge] and valved [cartridge]]**

**To [maintain] [install] directly fed configuration [use the cartridge model]**

<b>Inline Cartridge</b>	<b>Valved Cartridge</b>
1. Locate the main water supply for the chair and shut it off.	1. Locate the main water supply for the chair and shut it off.
2. Note the direction of water flow on the Cartridge label before going any further.	2. Find an install location near a water supply after selecting the appropriately sized Cartridge.
3. Ensure the waterline is long enough to be able to plug the 1/4" tubing into the IN and OUT portions on the cartridge and cut in the middle.	3. The location of the Filter Mounting Bracket depends on the Cartridge size. Leave ample room [2 inches] for Cartridge installation and replacement.
4. Sort out the fittings included in your CI-QK bag. Locate the Quick Release Fitting and remove the nut and collar from the male side.	4. Screw in the Mounting Bracket screws at the desired location. Do not tighten them all of the way so that the bracket can be installed.
5. Screw the nut and collar on. Tighten it with a wrench.	5. Make a cut on the water supply line where the inlet and outlet will reach the Cartridge.
6. Remove the blue protector cap from the end of the Cartridge.	6. Wrap the large threaded end of each Brass Compression Fitting with plumbers tape.
7. Wrap the threaded end of the 90-degree elbow fitting with plumbers tape and screw in the elbow fitting on both ends of the Cartridge, tightening with a wrench.	7. Screw the compression fittings into the valved head. Tighten with a wrench.
8. Wrap the female half of the Quick Release Fitting with plumbers tape and screw into the elbow fitting. Tighten with a wrench.	8. Ensure the IN and OUT connections are located on the proper sides for proper water flow direction.
9. Wrap the larger end of the Brass Compression Fitting with plumbers tape and screw into the other side of the Cartridge. Tighten with a wrench.	9. Attach the valved head into the Mounting Bracket using the 4 provided screws.
10. Insert the tubing onto the Quick Release Fitting and screw the nut and collar back onto the Fitting. Tighten it with a wrench.	10. Unscrew the hashmark nut and collar from the compression fittings.
11. Attach both parts of the Quick Release Fitting.	11. Put the nut onto the end of the 1/4" tubing that goes to the chair.
12. Turn on the water supply and check for leaks.	12. Slide the tubing onto the valved head on the OUT side and tighten the nut with a wrench.
13. Write the install and replacement dates on the Cartridge.	13. Repeat steps 11–12 on the opposite side labeled "IN".
14. Complete the Warranty Card registration online.	14. Hang the Mounting Bracket onto the screws in the wall and tighten them.
	15. Remove the yellow protector cap from the top of the Cartridge.
	16. Screw the Cartridge into the bottom of the valved head.
	17. Turn on the water supply and check for leaks.
	18. Write the installation and replacement dates on the label.
	19. Complete the Warranty Card registration online.

For replacement: [Inline][Turn off the water]. [Valved] Unscrew the cartridge from the setup kit and install a new cartridge.

[Note: Valved Cartridges must be mounted vertically to provide proper water treatment delivery]  
Visit [Sterisil.com](http://Sterisil.com) to watch the installation video

{Note to Reviewer: Language in [brackets] is optional.}

### **MAINTENANCE TREATMENT**

The [dental] water is automatically treated as it runs through the cartridge. Replace the Sterisil Dental Water Microbiological Cartridge, per the cartridge capacity and replacement schedule table.

[Sample cartridge life table (months)]

For specific details, please visit Sterisil.com

TDS (ppm)	CI-3i 2" x 6"	CI-6i 2" x 10"	CI-7i 2.5" x 8"	CI-9i 2.5" x 10"	CV-8 2.5" x 8.5"	CV-10 2.5" x 10"	CV-20 2.5" x 15"
0-50	4	10	11	12	8	12	12
51-75	3	6	7	10	6	10	12
76-100	2	4	5	7	4	8	12
101-150	1	3	4	5	3	5	8
151-200	1	2	3	4	2	4	6
201-250	1	2	2	3	2	3	5
250+	Ask Sterisil						

*[Note: cartridge lifespan [in table] is based on 240 liters each year.]*

Regularly monitoring the TDS level of outlet water is highly recommended for optimum performance. Replace the Cartridge [model] if the TDS level of outlet water exceeds 10 ppm. Handheld TDS meters are readily available for purchase direct from Sterisil.

### **{Stage 5 MODEL LANGUAGE}**

#### **[To [maintain] [install] Sterisil System configuration use the stage 5 model]**

1. Remove the [yellow or color] cap from the top of the [Stage 5] cartridge
2. Twist the cartridge into the threaded valve-head located in the stage 5 position.]

### **MAINTENANCE TREATMENT**

The [dental] water is automatically treated as it runs through the cartridge. Replace the Sterisil Dental Water Microbiological Cartridge, per the cartridge capacity and replacement schedule table.



{Note to Reviewer: Language in [brackets] is optional.}

### [Cartridge] Capacity & Replacement Schedule

{Note to reviewer: Only the appropriate section of this chart will appear on the label based on the model type selected.}

[Cartridge] Part No.	Net Contents (cc)	[Cartridge] Capacity	[Cartridge] Replacement	Water Type
<b>[Straw Model] (S#, #-V2, #L, #H)</b>				
<b>90</b>	4	60 L	90 days	[≤100 ppm TDS] [100 TDS or less]
<b>365</b>	8	240 L	1 year	[≤100 ppm TDS] [100 TDS or less]
<b>90m</b>	4	60 L	90 days	[100-250 ppm TDS] [>100 TDS]
<b>365m</b>	8	240 L	1 year	[100-250 ppm TDS] [>100 TDS]
<b>[Direct Feed Model] (CV-#, CI-#, C#)</b>				
<b>10</b>	8	240 L	All cartridges: 10 ppm TDS in treated water or 1 year, whichever comes first.	No greater than 250 ppm TDS
<b>20</b>	8	240 L		
<b>8</b>	8	240 L		
<b>7i</b>	20	240 L		
<b>3i</b>	20	240 L		
<b>9i</b>	20	240 L		
<b>6i</b>	20	240 L		
<b>[Stage 5 Model] (BP#, SS-#, C5-#)</b>				
<b>1</b>	120	1,000 L	Replace at rated capacity	To be used with a Sterisil System
<b>2.5</b>	133	2,500 L		
<b>3</b>	150	3,000 L		
<b>5</b>	200	5,000 L		
<b>7</b>	233	7,000 L		
<b>7.5</b>	250	7,500 L		
<b>10</b>	333	10,000 L		
<b>1T</b>	1000	30,000 L		
<b>2T</b>	2000	60,000 L		

#### [WARRANTY AND DISCLAIMER NOTICE:

The directions for use of this product are believed to be adequate and must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Sterisil® warrants the Sterisil Dental Water Microbiological Cartridge to be free from defects in parts, materials, manufacturing

{Note to Reviewer: Language in [brackets] is optional.}

or labor for the product rated period after the device is placed in use by the end user from the date of the purchase. If replacement is warranted, cost will be on a pro-rated basis.

To the extent consistent with applicable law, the products sold to you are furnished “as is” by Sterisil®. The manufacturer and the seller are subject only to the manufacturer’s warranties, if any, which appear on the label of the product sold to you. Except as warranted by this label, Sterisil®, the manufacturer, or the seller makes no warranties, guarantees, or representations of any kind to the buyer or the user, either express or implied, or by usage of trade, statutory or otherwise, with regard to the product sold or use of the product, including, but not limited to, merchantability or fitness for a particular purpose or use, or eligibility of the product for any particular trade usage. To the extent consistent with applicable law, Buyer’s or User’s exclusive remedy, and Sterisil®, the manufacturer’s or the seller’s total liability shall be limited to damages not exceeding the cost of the product. No agent or employee of Sterisil®, or the seller is authorized to amend the terms of this warranty disclaimer or the product’s label or to make a presentation or recommendation different from or inconsistent with the label of this product.

To the extent consistent with applicable law, Sterisil®, the manufacturer, or the seller shall not be liable for consequential, special, or indirect damages resulting from the use, handling, application, storage, or disposal of this product or for damages in the nature of penalties, and the buyer and the user waive any right that they may to such damages.]

{Note to Reviewer: Language in [brackets] is optional.}

**Optional Marketing Language – All Models - May appear on any label**

- 365 days of treatment
- 1 full year
- All-in-One
- All-in-one Cartridge
- All-in-one Straw
- [Cartridge] with a built-in shock treatment
- Contains no oxidizers.
- Does not contain iodine
- [Controls] [Reduces] [Inhibits] odor-causing bacterial contamination in [dental unit water lines] [effluent water]
- Controls odor-causing bacteria in dental unit water lines.
- Dental waterline treatment
- Does not contain iodine. May be used to comply with Best Management Practices that prohibit cleaning with oxidizing or acidic cleaners.
- 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
- Sterisil cartridge
- Shock included
- Suitable for patients and clinicians
- [Say] goodbye [to] tablets [Hello [to] Convenience]
- [Straw] [with a] built-in shock treatment
- Treats dental unit waterlines
- Waterline treatment made easy and reliable
- Waterline responsibility
- High [hardness] [TDS] [straw]
- Low [hardness] [TDS] [straw]
- Your complete dental waterline solution
- Complete waterline treatment solution
- It is recommended to shock the dental unit waterlines monthly with Citrisil Shock Tablets
- No iodine taste in water
- May need to perform additional shock treatments using shock tablets to lower odor-causing bacteria count (CFU/mL)
- Odor free
- Replacement time based on average [non-surgical] dental [procedural] water usage
- Antimicrobial cleaner
- Clean and maintains dental [unit] waterlines
- Designed to deliver
- Visit us online at Sterisil.com
- Dental [unit] waterline [product]
- No more tablets
- Dental Waterline antimicrobial [unit][cartridge][straw]
- Waterline control
- Additional shocks may be required for first time users

*Sterisil Dental Water Microbiological Cartridge (83315-2)*

Sterisil, Inc.

Amendment – December 19, 2019, Label Version (3) June 22, 2020

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{Note to Reviewer: Language in [brackets] is optional.}

- Sterisil
- Sterisil Straw
- Sterisil Dental Water Antimicrobial
- Sterisil Dental Waterline Antimicrobial Cartridge
- [[[Sterisil] [Waterline] [Antimicrobial]] Cartridge]
- Sterisil Straw V2

\*Controls odor-causing bacteria

Optional Quick Identifier

[Model Type] [[Straw/Bottle/Stage 5/Direct Feed/Municipal/Cartridge/System]

[Model/Type/Size/Box]]

[[Straw/Bottle/Stage 5/Direct Feed/Municipal/Cartridge/System] Configuration]

[[Configured for [Bottle/System/Direct Feed] [Applications/Arrangements/Setups]]

ISO 13485 approved address and symbols

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