



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 22, 2017

Abigail T. D. Wacek
Regulatory Consultant
Sterisil, Inc.
835 S. Hwy 105, Suite D
Palmer Lake, CO 80133

Subject: Label Amendment – Updating the Format and Multiple Sections of the Label
Product Name: Sterisil Dental Water Microbiological Cartridge
EPA Registration Number: 83315-2
Application Date: 11/18/2016
Decision Number: 523999

Dear Mrs. Wacek:

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.

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.

The alternate brand name "Sterisil Straw" has been added to the product record.

Page 2 of 2
EPA Reg. No. 83315-2
Decision No. 523999

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 Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "John Hebert" with a stylized flourish at the end.

John Hebert, Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped Label

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

Sterisil Dental Water Microbiological Cartridge

[Alternate Brand Name: Sterisil Straw]

[All-In-One] Dental Water Microbiological Cartridge

Sterisil Dental Water Microbiological Cartridges are formulated and clinically proven to kill odor causing bacteria, maintain dental unit water line effluent ≤ 10 CFU/ml, 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 INSTRUCTIONS FOR FUTURE USE Only selected information is contained on the cartridge packaging

Active Ingredient Silver*	17.5
Inert Ingredients	<u>82.5</u>
Total	100.0

*bound to hydrogen form weak acid gelular cation exchange resin

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION In the event of a rupture of the cartridge avoid contact with the silver ion exchange resin which may cause eye and skin irritation. Avoid direct contact with eyes skin and 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. If cartridge breaks, place debris into a sealed plastic bag and discard in trash.

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
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.

ENVIRONMENTAL HAZARDS Silver is toxic to fish and aquatic invertebrates

STORAGE AND DISPOSAL

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

STORAGE

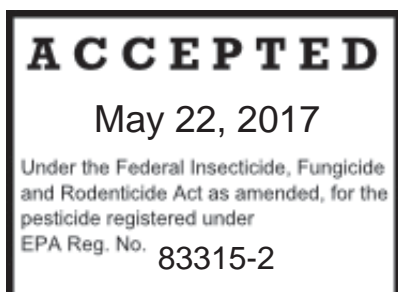
Store in a cool dry area out of direct sunlight.

PESTICIDE DISPOSAL

Securely wrap cartridge in newspaper and 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

Dispose of empty packaging in trash.



Sterisil Dental Water Microbiological Cartridge (83315-2)
Sterisil, Inc.

Amendment – November 18, 2016, Label Version (5), May 12, 2017

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

DIRECTIONS FOR USE

[Refer to reverse side of this sheet]

EPA Reg. No. 83315-2
EPA Est. No. 83315-CO-001

Sterisil Inc.
835 S Hwy 105 Suite D
Palmer Lake CO 80133

719 622 7200 or online at Sterisil.com

Patent No 6 991 736

DIRECTIONS FOR USE

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

INITIAL INSTALLATION

Sterisil® Straw Cartridge Models:

[Attach the cartridge to the new 1/4" pick-up tube provided. Cut the pick-up tube to the appropriate length so the cartridge extends to the bottom of the bottle.

*Use only the Sterisil® Straw 90m or 365m for municipal water which exceeds 100 ppm total dissolved solids.]

OR

[Cut the existing pickup tube to appropriate length so, when the Straw Cartridge is attached, it will extend within ¼" of the bottom of the bottle. Insert the barb provided onto the end of the pickup tube. Remove the shrink wrapping from the straw, then twist off the orange cap on the top of the straw. Hold the barb firmly and twist the cartridge counterclockwise onto the barb.

*Use only the Sterisil Straw S90m or S365m for municipal water which exceeds 100 ppm total dissolved solids.]

Sterisil® Cartridge and System Models:

Connect the cartridge to the dental unit's incoming potable water supply by inserting cartridge into threaded valve-head assembly or ¼" threaded fitting if cartridge is an in-line version.

INITIAL TREATMENT

All Cartridge Models:

Sterisil® Dental Water Microbiological Cartridges are engineered to automatically produce a "shock" treatment after initial connection and treatment of dental water. Run all lines attached to the dental units until blue coloration appears exiting the lines. Allow lines to remain unused for a minimum of 8 hours.

Prior to use of dental unit flush dental lines until blue color disappears (approximately 4 ounces).

Sterisil Dental Water Microbiological Cartridge (83315-2)

Sterisil, Inc.

Amendment – November 18, 2016, Label Version (5), May 12, 2017

2 of 5

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

MAINTENANCE TREATMENT

Sterisil® Straw Cartridge Models:

Fill independent water bottle with distilled or deionized water. The dental water is automatically treated as it runs through the cartridge. Replace the cartridge per the Cartridge Capacity & Replacement Schedule.

Sterisil® Cartridge and System Models:

The dental water is automatically treated as it runs through the cartridge.

Replace the **Sterisil® cartridge** after 1-year or when the Total Dissolved Solids (TDS) content in the treated water exceeds 10 ppm, whichever comes first.

Replace the **Sterisil® System** cartridge at the rated treated volume.

Cartridge Capacity & Replacement Schedule

Cartridge/REF Straw Part No.	Net Contents (cc)	Suggested Cartridge/Straw Capacity	Cartridge/Straw Replacement
Straw (S#, V2#)			
90	4	60 L	90 days
365	8	240 L	1 year
90m	4	60 L	90 days
365m	8	240 L	1 year
*m – used with municipal water source			
Cartridge (C#)			
10	8	240 L	All cartridges: 10 ppm TDS in treated water or 1 year, which ever comes first.
20	8	240 L	
8	8	240 L	
7i	8	240 L	
3i	8	240 L	
9i	8	240 L	
6i	8	240 L	
*i – inline cartridge			
System (BP#)			
1	12	1,000 L	Replace at rated capacity
3	100	3,000 L	
7	233	7,000 L	
10	333	10,000 L	
1T	1000	30,000 L	
2T	2000	60,000 L	

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

Go to the Sterisil website [for help selecting the appropriate cartridge] [to access the CARTRIDGE CALCULATOR for help selecting which size cartridge will best suit your office] [<https://www.sterisil.com/cartridge-calculator>].

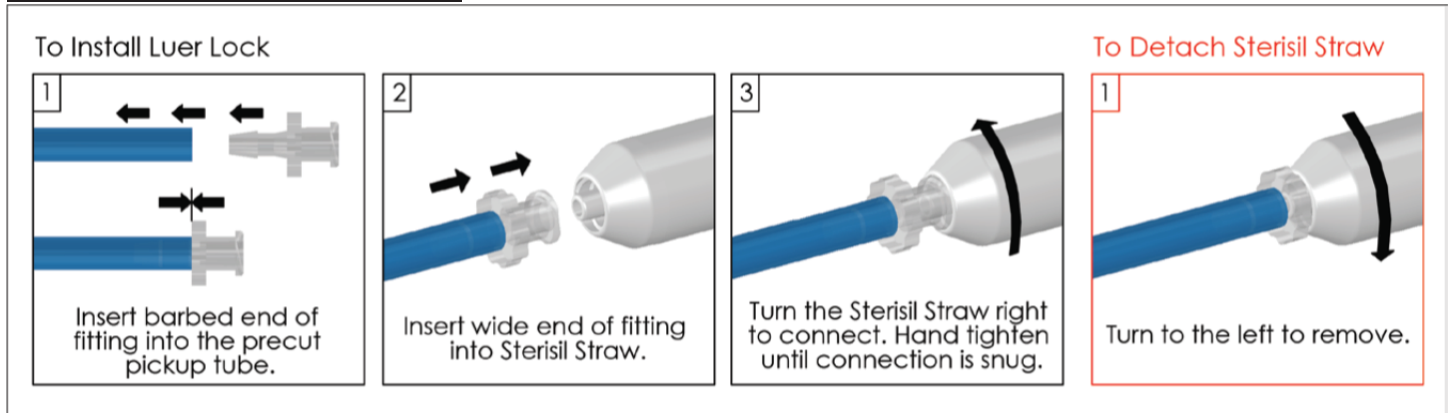
WARRANTY STATEMENT

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® products to be free from defects in parts, materials, manufacturing 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, 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 the 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.

SUPPLEMENTAL USER INSTRUCTIONS



The Sterisil Straw comes with a Luer Lock. Proper installation of the luer lock is shown in the diagrams. It is important to cut the existing pickup tube to the proper length so that the bottom of the Sterisil Straw is at least a 1/4” from the bottom of the bottle.

Sterisil Dental Water Microbiological Cartridge (83315-2)

Sterisil, Inc.

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4 of 5

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

It is recommend you use a Sterisil Antimicrobial Bottle™ [alternate brand name: BioFree® Bottle] and clean your bottle once a year with a Citrisil™ Shock tablet to maintain the antimicrobial efficacy. If you have not purchased a Sterisil Antimicrobial Bottle™ [alternate brand name: BioFree® Bottle] we recommend you clean your bottles once a month with a Citrisil™ Shock tablet to inhibit the growth of any microorganisms that may be present.

FOR OPTIMAL STRAW PERFORMANCE: Source water for the S90/S365 should read 100 ppm or less on a Total Dissolve Solid (TDS) meter. Source water for S90m/ S365m should read greater than 100 ppm, but no more than 250 ppm, on a Total Dissolved Solids (TDS) meter. If source water is greater than 250 ppm on a Total Dissolved Solid (TDS) meter, use distilled water with a distilled straw.

[SUPPLEMENTAL USER INSTRUCTIONS CONTINUED:]

ATTENTION! WARRANTY VOID IF NOT REGISTERED WITHIN 2 WEEKS OF INSTALLATION!
GO TO WWW.STERISIL.COM/WARRANTY OR CALL 719-622-7200