



**U.S. ENVIRONMENTAL PROTECTION AGENCY**  
 Office of Pesticide Programs  
 Antimicrobials Division (7510P)  
 1200 Pennsylvania Avenue NW  
 Washington, D.C. 20460

EPA Reg. Number:  
 83315-2

Date of Issuance:  
 MAY 15 2009

Term of Issuance:  
**Conditional**

Name of Pesticide Product:  
 Sterisil Dental Water  
 Microbiological  
 Cartridge

**NOTICE OF PESTICIDE:**

- Registration
- Reregistration

(under FIFRA, as amended)

Brad Downs  
 Sterisil, Inc.  
 835 S. Hwy. 105, Unit D  
 Palmer Lake, CO 80133

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No. 83315-2".

Signature of Approving Official: \_\_\_\_\_

Marshall Swindell  
 Product Manager Team-33  
 Regulatory Management Branch I  
 Antimicrobials Division (7510P)

Date:

MAY 15 2009

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- b. Under the **Directions for Use** section, **Cartridge Capacity & Replacement Schedule**, delete the 5 year claim. *Empirical* data has been submitted for the 1 year release rate study for silver resin. *Calculated* data was submitted for the 5 year claim. To support that 5 year time frame, empirical data must be submitted

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell  
Product Manager Team-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: (Stamped Label)

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# Sterisil® Dental Water Microbiological Cartridge

Sterisil® Dental Water Microbiological Cartridges are formulated and clinically proven to kill odor causing bacteria, maintains 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.

EPA Company No. 083315  
EPA Reg. No. 083315-E  
Patent No. 6,991,736

PLEASE SAVE THESE INSTRUCTIONS FOR FUTURE USE. Only selected information is contained on the cartridge packaging.

KEEP OUT OF REACH OF CHILDREN

## CAUTION

Active Ingredient: Silver\*...17.5%  
Inert Ingredients:..... 82.5%  
Total:.....100 %

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

Manufactured by  
Sterisil, Inc.  
835 S. Hwy. 105, Unit D  
Palmer Lake, CO 80133

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

RECEIVED  
MAY 15 2009  
under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No  
83315-2

## 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. Place debris into a sealed plastic bag and discard in trash.

### ENVIRONMENTAL HAZARDS

Silver is toxic to fish and aquatic invertebrates.

### DIRECTIONS FOR USE

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

NET CONTENTS: Microbiological Water Microbiological Cartridge

### Cartridge Capacity & Replacement Schedule

Cartridge Part No.	Silver Impregnated Resin (cc)	Suggested Cartridge Capacity	Cartridge Replacement
<b>Puretube™ (PT#), BioPYÜR™ Straw (S#)</b>			
90	4	60 L	90 days
365	8	240 L	1 year
<del>375</del>	<del>12</del>	<del>1200 L</del>	<del>6 years</del>
90m	4	60 L	90 days
365m	8	240 L	1 year
<b>*m - used with municipal water source</b>			
<b>Puretube Plus™ (PTP#), BioPYÜR™ Cartridge (C#)</b>			
10	8	240 L	All PTP cartridges: 10 ppm TDS in treated water or 1 year; whichever 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	
<b>*i - inline cartridge</b>			
<b>Pureline 50 Max™ (PL#), BioPYÜR™ System (BP#)</b>			
1	12	1,000 L	
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	

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**INITIAL INSTALLATION**

**Puretube™ 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. Fill bottle with distilled or deionized water. If using municipal water, confirm that the water quality is good and has less than 3 grains hardness.

\*Use only the Puretube 90m or 365m for municipal water.

**Puretube Plus™, Pureline 50 MAX™ and BioPYÜR™ Cartridge Models:**

Connect the cartridge to the dental unit's incoming potable water supply by inserting cartridge into threaded valve-head assembly or 1/4" 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 12 hours.

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

**MAINTENANCE TREATMENT**

**Puretube™ 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.

**Puretube Plus™, Pureline 50 Max™ and BioPYÜR™ Cartridge Models:**

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

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

Replace the Pureline 50 Max™ or BioPYÜR™ cartridge at the rated treated volume.

**STORAGE AND DISPOSAL**

**STORAGE**

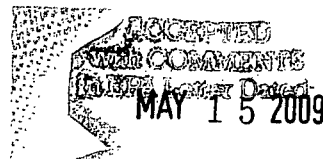
Store in a cool dry area out of direct sunlight. Do not contaminate water, food or feed by storage or disposal.

**DISPOSAL OF UNUSED PRODUCT**

Empty container by using product according to label directions. Return Pureline cartridge to Sterisil® for recycling.

**CONTAINER DISPOSAL**

Dispose of empty packaging in trash. Return Pureline 50 Max™ or BioPYÜR™ cartridge to Sterisil® for recycling.



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

83315-2