



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Antimicrobials Division (7510P)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg. Number:  
83315-1

Date of Issuance:  
**MAY 15 2009**

Term of Issuance:  
**Conditional**

Name of Pesticide Product:  
Citrisil

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. 83315-1".

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, No. 9, delete the wording “existing biofilm”. Efficacy data needs to be submitted to support this claim. Insert the following language “existing odor causing bacteria”.
- c. Under the **Storage and Disposal** statement, add the following language under the **Container Disposal** section: “**Nonrefillable Container. Do not re-use this container. Dispose of empty foil pouch in the trash**”.

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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# Citrisil™

## Dental Waterline Microbial Contaminant Control Tablet

Citrisil™ is specially formulated and clinically proven to:

- Kill odor causing bacteria
- Maintains dental unit water line effluent ≤ 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.

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

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

KEEP OUT OF REACH OF CHILDREN

*(Residual odor causing bacteria)*

## CAUTION

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

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Solid tablet 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.

### ENVIRONMENTAL HAZARDS

Silver is toxic to fish and aquatic invertebrates.

### PHYSICAL or CHEMICAL HAZARDS

The Product will react with strong acids or oxidizing agents.

## DIRECTIONS FOR USE

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

### Use Citrisil Shock™ Before Regular Use of Citrisil™ Tablets:

1. Empty water from bottle.
2. Press orange Citrisil Shock™ tablet into bottle.
3. Add 177 ml. (6 fl.oz.) of warm **distilled water**.
4. Wait 60 seconds for tablet to fully dissolve.
5. Swirl orange shock solution to clean and disinfect inside of bottle.
6. Connect bottle to dental unit and run lines until orange color appears.
7. Leave in lines overnight.
8. The following day empty orange shock solution from bottle.
9. For initial use of Citrisil Shock™ repeat steps 1 through 8 two additional times to eradicate ~~odor~~ (additional Citrisil Shock™ tablets can be purchased separately). Thereafter, use Citrisil Shock™ with each new box of Citrisil™ or monthly, whichever comes first.

### Regular Use of Citrisil™ 90 mg Tablets:

10. Add 1 tablet into an empty 0.7 liter (24 fl.oz.) or 1 liter (34 fl.oz) water bottle by pressing tablet through blister packaging directly into the bottle (add 2 tablets for 2 liter (68 fl.oz.) bottles).
11. Fill bottle with **distilled or purified tap\* water**, wait 60 seconds for tablet(s) to dissolve, connect bottle to dental unit.
12. If just completing Citrisil Shock™ treatment, purge waterlines until orange color dissipates.
13. Initiate patient care.
14. When bottle is empty repeat Steps 10 and 11.

### Regular Use of Citrisil™ 180 mg Tablets:

15. Add 1 tablet into an empty 1.5 l (51 fl. oz.) or 2 liter (68 fl. oz.) water bottle by pressing tablet through blister packaging directly into the bottle.

16. If just completing Citrisil Shock™ treatment, purge waterlines until orange color dissipates.
17. Initiate patient care.
18. When bottle is empty repeat Steps 15 through 17.

## ALTERNATE FORMULATION

For easy visual compliance, use the alternate CitriSil Blue™ tablet which provides a light blue color in the treated water.

**NOTE:** Test output water bacteria level after startup and at appropriate intervals based on results. Clinical monitoring of bacteria levels can ensure that procedures are being performed correctly and are effective. Contact Sterisil for assistance with in-office or independent third party water testing.

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.

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

## 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.

### CONTAINER DISPOSAL

~~Do not reuse container for any other purpose.~~

### WARRANTY STATEMENT

Exposure to moisture may reduce tablet effervescent ability. Exposure to direct light may cause tablet to change color.

Net Contents:  
1 Citrisil Shock™ with 180 mg Tablets  
20 Citrisil™ Microbial Control Tablets

Manufactured by Sterisil, Inc.  
835 S. Highway 106  
Palmer Lake, Colorado 80459  
EPA Reg. No. 083315-R  
EPA Company No. 083315  
Federal Insecticide, Fungicide and Rodenticide Act amended, for the pesticide, registered under EPA Reg. No.

83315-1