

NOV 16 1988

Environmental Control Systems, Inc.  
Route 1, Box 21  
Churchill, MD 21623

Attention: Frank J. Bonarrigo

Gentlemen:

Subject: Steri-Plus 128 Disinfectant  
EPA Registration No. 10854-7  
Your Submission Dated December 18, 1987  
EPA Received Date December 21, 1987

The submission referred to above, submitted in connection with the Label Improvement Program Notice for Antimicrobial Products Used as Food Contact Surface Sanitizers, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. Revise the sentence "a pre-cleaning step is required and recommended" to "a pre-cleaning step is required."
  - b. In the "Note to Physician" section, delete the last two sentences starting with "measures against . . . ."
  - c. Delete the word "milk."
  - d. In the active ingredient section delete Tetrasodium ethylenediamine tetraacetate sodium carbonate and Essential Oils. They are now considered inert ingredients. Adjust your inert ingredients percentages accordingly.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment.

50233: I:DeLaney:LL-6:KENCO:10/17/88:11/30/88:DD:EK:VO:AS

CONCURRENCES

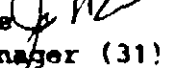
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|        |         |      |  |  |  |  |  |

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A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please call Ms. Karen Leavy at (703) 557-3966.

Sincerely yours,

  
John H. Lee  
Product Manager (31)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosure

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

STERI PLUS 128 detergent/disinfectant has been designed specifically for hospitals, nursing homes, schools, and other institutions where housekeeping is of prime importance.

**DISINFECTION** - To disinfect hard inanimate surfaces (such as walls, floors, table tops) add (1) one ounce of STERI PLUS 128 detergent/disinfectant per gallon of water. Apply solution with mop, cloth, or sponge or mechanical sprayer so as to wet thoroughly. Allow to remain wet for 10 minutes and then let air dry.

To disinfect toilet bowls, flush toilet, add (1) one ounce STERI PLUS 128 detergent/disinfectant directly to the bowl water. Scub the bowl completely using a scrub brush or toilet mop, making sure to get under the rim. Let stand for 10 minutes and flush.

For heavily soiled areas a pre-cleaning step is required and recommended. Prepare a fresh solution for each use.

**MILDESTAT** - To control mold and mildew on pre-cleaned, hard nonporous surfaces (such as floors, walls, table tops) add (1) one ounce STERI PLUS 128 detergent/disinfectant per gallon of water. Apply solution with a cloth, mop, or sponge making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application at weekly intervals or when mildew growth reappears.



STERI PLUS 128 is designed specifically for hospitals, schools and other institutions where housekeeping is of prime importance and where contamination is a constant problem.

STERI PLUS 128 when diluted with water (one ounce per gallon of water) acts against the organisms which require special attention. STERI PLUS 128 disinfects hard surfaces such as floors, walls, tables, chairs, and other areas. It is also used for both general cleaning and disinfection.

In addition, STERI PLUS 128 is generally used for storage areas, empty rooms, and any other areas where microorganisms are present.

**DISINFECTION** - At (1) ounce per gallon of water STERI PLUS 128 disinfects the following: *Pseudomonas aeruginosa*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella schottmuelleri*, *Salmonella choleraesuis*, *Streptococcus salivarius*. At this level the product is effective against pathogenic fungi *Trich*

**VIRUCIDAL\* ACTIVITY:** STERI PLUS 128 disinfects inanimate hard surfaces and exhibits effective virucidal activity against Asian (representative of influenza) and vaccinia virus type 2 (causative agent of smallpox) and Vaccinia virus (re-

**EFFICACY TESTS HAVE DEMONSTRATED THE EFFECTIVE BACTERICIDAL, FUNGICIDAL, AND VIRUCIDAL PRESENCE OF ORGANIC SO**

**MOLD and MILDESTAT** - STERI PLUS 128 disinfects mold and mildew on hard surfaces.

CLEANSER  
DETERGENT  
DEODORIZER

DISINFECTANT  
FUNGICIDE (against  
pathogenic fungi)  
VIRUCIDE\*

MILDESTAT (on hard inanimate surfaces)

**ACTIVE INGREDIENTS:**

|   |                |                |
|---|----------------|----------------|
| Active Ingredients:   |                |                |
| n-Alkyl (C-14 60%, C-16 30%, C-12 5%, C-14 5%) dimethyl benzyl ammonium chlorides | 4.50%          | 4.50%          |
| n-Alkyl (C-12 55%, C-14 32%) dimethyl ethylbenzyl ammonium chlorides              | 4.50%          | 4.50%          |
| <del>...</del>  | <del>...</del> | <del>...</del> |
| <del>...</del>  | <del>...</del> | <del>...</del> |

**INERT INGREDIENTS**

EPA REG. NO. 10854-7  
EPA EST. NO. 10854-10-1

KEEP OUT OF REACH OF CHILDREN  
DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED  
with COMMENTS  
by EPA Lab. 1/10/77

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 10854-7

**PRECAUTIONARY STATEMENTS**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
DANGER

KEEP OUT OF REACH OF CHILDREN. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

**STATEMENT OF PRACTICAL TREATMENT**

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of water, egg whites, gelatin solution or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately.

**NOTE TO PHYSICIAN**

Probable mucosal damage may contraindicate the use of gastric lavage. ...

**Environmental Control Systems, inc.**  
301-556-6611

**IN THE SERVICE OF MAN THROUGH THE SCIENCE OF CHEMISTRY.**

101 Rt. 1, Box 21 Church Hill, MD 21623

**DO NOT CONTAMINATE OR DISPOSAL**  
**STORAGE:** Store in a cool, dry place or higher than 120°F.  
**PESTICIDE DISPOSAL:** Improper disposal of this product is a violation of Federal Law. Use according to label directions. Environmental Control Systems, Inc. is the nearest Environmental Control Systems, Inc. representative at the nearest Environmental Control Systems, Inc. representative.  
**CONTAINER DISPOSAL:** Rinse empty containers thoroughly with water before reconditioning or puncturing. Other procedures approved by local authorities may be disposed of if allowed by local authorities.