

1043-83

8-27-2003

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 27 2003

Michael G. Sarli  
Sr. Regulatory Specialist  
Steris Corp.  
P.O. Box 147  
St. Louis, MO 63166-0647

SUBJECT: Coverage Spray Disinfectant Cleaner  
EPA Registration Number: 1043-83  
Application Dated: May 22, 2003  
Receipt Date: June 11, 2003

Dear Mr. Sarli:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable subject to the conditions listed below.

- Update as per PR Notice 2001-1

**Conditions**

Revise the label as follows:

1. Revise the "Ingredients Statement" to include the phrase "Total.....100%"
2. As per PR Notice 2001-1, the First Aid statements are to be ordered from most toxic to least toxic route of exposure. Thus revise such that "If in Eyes" is followed by "If on skin or clothing" then "If swallowed" and finally "If Inhaled."
3. Delete the heading "Hotline Number" since you have not indicated that you intend to place a hot line number in this section.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	J. Sarli						
DATE	8/21/03						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/4

4. Revise the section which begins: "Coverage Spray Disinfectant Cleaner is designed for general cleaning and..." to state: "...inanimate hard non-porous surfaces such as..."

5. Your product is for use in Hospitals and you have included the surface "bed springs." Thus you must add the MOU statement as per PR Notice 94-4:

"This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

6. Abbreviated names of public health organisms are not acceptable. Revise to state: "This product is fungicidal against pathogenic fungi *Trichophyton Mentagrophytes* when used..."

7. Since you have indicated that this product is only marketed in 22 ounce plastic containers, revise the "Storage and Disposal" section as follows:

**"Storage and Disposal**

Store in a dry place no lower in temperature than 50°F or higher than 120°F.

Do not reuse empty container. Wrap container and put in trash."

Delete the remaining language in this section as it is not required for your container type and size.

8. Your Precautionary language is not in agreement with the label review manual and as such revise the "Precautionary Statements" to read exactly as follows:

"Cause substantial but temporary eye injury and skin irritation. Do not get in eyes, on skin, or clothing. Wear protective eyewear (goggles or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

9. Revise directions for use as follows:

A. to list only hard non-porous surfaces by indicating: "glazed bathroom tiles."

B. "Allow the product to saturate area and remain wet..."

C. "For heavily soiled areas preclean to remove gross..."

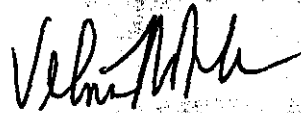
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**General Comments**

A stamped copy of the labeling accepted with comments is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure: Stamped Label  
7510C:T.Lantz:8/21/03:1043-83

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**Precautionary Statements  
Hazard to Humans and Domestic Animals  
WARNING**

Causes eye and skin irritation. Do not get in eyes, skin or on clothing.  
Wash thoroughly with soap and water after using.

**DIRECTIONS FOR USE**

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

Coverage Spray Disinfectant Cleaner has been designed specifically for Institutional, Commercial, and Industrial cleaning and disinfecting in Nursing Homes, Hospitals, Offices, Schools, Motels and Hotels, Recreational Facilities and Factories.

**DISINFECTION, CLEANING, AND DEODORIZING.** To disinfect, clean, and deodorize hard non-porous surfaces such as bathroom tiles, fixtures, shower stalls, walls, sinks and bathtubs, hampers, tables, chairs and counters:

Hold container six to eight inches from surface to be treated and spray area until it is covered with foam. Allow the product to penetrate and remain wet for 10 minutes. No scrubbing is necessary. Wipe off with a clean cloth, mop, or sponge. The product will not leave grit or soap scum. For heavily soiled areas, remove gross soil before treatment.

**MILDEWSTAT-** To control mold and mildew on hard non-porous surfaces such as floors, walls, table tops, spray the surfaces to be treated, making sure to wet completely with foam. Let air dry. Repeat application at weekly intervals or when mildew growth reappears.

EPA Reg. No. 1043-83 EPA Est. No. 1043-MO-2

STERIS Corporation

7501 Page Avenue  
St. Louis MO 63133 U.S.A.

**COVERAGE® SPRAY  
DISINFECTANT CLEANER**

**Cleaner • Virucide\* • Deodorizer • Disinfectant  
Mildewstat (on hard inanimate non-porous surfaces)**

**Active Ingredients**

n-Alkyl (60% C<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)  
dimethyl benzyl ammonium chlorides..... 0.105%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>) dimethyl  
ethyl benzyl ammonium chlorides..... 0.105%  
**Inert Ingredients:** ..... 99.790%

**KEEP OUT OF REACH OF CHILDREN  
WARNING**

See side panel for additional precautionary statements

FIRST AID	
If inhaled	<ul style="list-style-type: none"> <li>•Move person to fresh air.</li> <li>•If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>•Call a poison control center or doctor for further treatment advice.</li> </ul>
If on skin or clothing	<ul style="list-style-type: none"> <li>•Take off contaminated clothing.</li> <li>•Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If in eyes	<ul style="list-style-type: none"> <li>•Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>•Remove contact lenses, if present, after the first 5 minutes, then continue rinsing the eye.</li> <li>•Call a poison control center or doctor for treatment advice.</li> </ul>
If swallowed	<ul style="list-style-type: none"> <li>•Call poison control center or doctor immediately for treatment advice.</li> <li>•Have person sip a glass of water if able to swallow.</li> <li>•Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>•Do not give anything by mouth to an unconscious person.</li> </ul>
HOTLINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

Net Contents:

Coverage Spray Disinfectant Cleaner is designed for general cleaning and disinfecting in Nursing Homes, Hospitals, Institutions, Offices, Schools, Motels and Hotels, Recreational Facilities and Factories. When used as directed, it is formulated to disinfect inanimate hard surfaces such as walls, sink tops, tables, chairs, telephones, door knobs, light switches, shower stalls, hampers, cabinets, and bed springs.

In addition, it deodorizes those areas which generally are hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, basements, restrooms, and other areas which are prone to odors caused by microorganisms.

When used as directed, Coverage Spray Disinfectant Cleaner demonstrates effective disinfection against Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa, thus meeting requirements for hospital use. Efficacy tests have demonstrated that it is an effective one-step cleaner-disinfectant in the presence of organic soil (5% blood serum).

The product is fungicidal against pathogenic fungi (T. Mentagrophytes) when used as directed on hard surfaces found in the bathroom, shower stall, and locker room, or other clean hard non-porous surfaces commonly contacted by bare feet.

\*Coverage Spray Disinfectant Cleaner is effective only against the lipophilic virus, Herpes Simplex Type 2, when used as directed on washable hard non-porous environmental surfaces.

**MOLD AND MILDEWSTAT-** this product prevents and controls mold and mildew and the odors they cause on hard non-porous inanimate surfaces.

**STORAGE AND DISPOSAL  
DO NOT CONTAMINATE WATER, FOOD, OR FEED BY  
STORAGE OR DISPOSAL**

**PESTICIDE STORAGE -** Store in a dry place no lower in temperature than 50°F or higher than 120°F.

**CONTAINER DISPOSAL -** Do not reuse empty container. Wrap container and put in trash.

**PESTICIDE DISPOSAL -** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**ACCEPTED**  
with COMMENTS  
in EPA Letter Dated:

AUG 27 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. #1043-83

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