

APR 05 1998

Lonza, Inc.  
 c/o 122 C Street, N.W., Suite 740  
 Washington, D.C. 20001

Attention: Wendy A. McCombie  
 Agent for Lonza, Inc.

Subject: CSP - 46 - Additional Organisms & Label Claims  
 EPA Registration No. 6836-245  
 Your Submission Dated September 30, 1997  
 Your Submission Received October 7, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, will be acceptable provided that you make the labeling changes listed below before you release the product for shipment bearing the amended label.

1. The use of the label claim kills germs is considered to be synonymous to a sterilizing claim and is considered unwarranted and unacceptable. Refer to item D-301 in the enclosure.
2. On the middle of the left panel of page two, revise "CSP-46 removes dirt and grime and kills germs" to read "CSP-46 removes dirt and grime and kills many germs."
3. In the middle panel of page two, revise "CSP-46 kills germs and bacteria and cuts grease and grime" to read "CSP-46 kills many germs and bacteria and cuts grease and grime."
4. On the right middle panel, revise "...CSP-46 concentrate is an..." to read "...CSP-46 is an..."
5. On the bottom right panel of page two, revise "CSP-46 kills germs that cause bad odors" to read "CSP-46 kills many germs that cause bad odors."
6. Also, on the bottom right panel, revise "CSP-46 cleans today's soils and disinfects today's germs" to read "CSP-46 cleans today's soils and disinfects today's many germs."

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SYMBOL	7510W						
SURNAME	J.Fairfax						
DATE	4/5/98						

7. On page three, right panel, revise "Virucidal according to the virucidal qualification" to read "Virucidal on hard, nonporous inanimate surfaces according to the virucidal qualification."


8. On page four, in the Directions for Use, under the "Sanitizing Non-Food Contact Surface Directions" section of the label, delete "porous" since the submitted and accepted sanitizing data for this product only supports a usage for hard, nonporous surfaces.

A stamped copy of the labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

The submitted efficacy data were found acceptable and have been included in the file for this product.

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,



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

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**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**CAUTION.** Causes eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

**FIRST AID**

**IF ON SKIN:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF IN EYES:** Flush eyes with plenty of water. Call a physician if irritation persists.

*(If the container size is 5 gallons or greater, use the following Environmental Hazards statements:)*

**ENVIRONMENTAL HAZARDS**

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**PHYSICAL OR CHEMICAL HAZARDS**

Do not store near heat or open flame.

*(If the container size is greater than 1 gallon, use the following Storage and Disposal statements:)*

**STORAGE AND DISPOSAL**

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

**Pesticide Disposal:** Wastes resulting from this product may be disposed of on-site or at an approved waste disposal facility.

**Container Disposal:** (metal): Triple rinse (or equivalent).

Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by procedures approved by state and local authorities. (plastic containers greater than 1 gallon). Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

*(If the container size is 1 gallon or less, use the following storage and disposal statement:)*

**STORAGE AND DISPOSAL**

Do not reuse bottle except with CSP-46. If not refilling, discard in trash.

**CSP-46**

**Glass and Surface Cleaner**  
**Hospital Use Disinfectant, Bactericide,**  
**Fungicide, Virucide\*, Sanitizer and Deodorizer**  
**For Hospital, Commercial, Institutional, Industrial**  
**and Household Use**

**Active Ingredients:**

n-Alkyl (C<sub>14</sub>-60%, C<sub>16</sub>-30%, C<sub>12</sub>-5%, C<sub>18</sub>-5%)  
**Dimethyl Benzyl Ammonium Chloride** ... 0.05%  
n-Alkyl (C<sub>12</sub>-68%, C<sub>14</sub>-32%) **Dimethyl**  
**Ethylbenzyl Ammonium Chloride** ..... 0.05%  
**Inert Ingredients** ..... 99.90%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**SEE SIDE PANEL FOR ADDITIONAL**  
**PRECAUTIONARY STATEMENTS**

EPA Reg. No. 6836-245

EPA Est. No.

**Net Contents:**

**Manufactured by:**

**Lonza Inc.**

**17-17 Route 208**

**Fair Lawn, NJ 07410**

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

**APR 05 1998**

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

6836-245

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Bactericidal cross-contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. **CSP-46** has been formulated to aid in the control of cross-contamination from treated surfaces in these areas.

**CSP-46** is a one-step disinfectant cleaner that is effective against a broad spectrum of bacteria.

When used as directed **CSP-46** will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and other places where bacterial growth can cause mal odors.

**CSP-46** is recommended for use in hospitals, medical and dental offices, nursing homes, veterinary clinics, public rest rooms, institutions, schools, colleges, athletic facilities, food processing plants, food storage areas, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels.

**CSP-46** uses an anti-bacterial formula to cut grease, grime and to disinfect.

**CSP-46** kills germs such as *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa*.

**CSP-46** removes dirt and grime and kills germs.

**CSP-46** kills germs and bacteria and cuts grease and grime.

**CSP-46** disinfects and deodorizes.

**CSP-46** cleans tough dirt while leaving a fresh, clean, scent.

**CSP-46** cleans and deodorizes.

**CSP-46** cuts grease and deodorizes.

**CSP-46** cuts grease, grime and deodorizes.

For use in households.

Contains no phosphorous, butyl cellosolve or butoxyethanol.

Contains no ammonia.

Contains biodegradable cleaning agents.

Contains cleaning agents, perfume, dye and water.

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**CSP-46** cleans and deodorizes and cuts grease and grime.

**CSP-46** is a no-rinse cleaner that disinfects, cleans and deodorizes in one labor saving step.

**CSP-46** cleans, shines, deodorizes and disinfects hard, non-porous household surfaces.

**CSP-46** is for use in kitchens, bathrooms, and other household areas.

**CSP-46** kills household germs in 10 minutes; effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis*.

**CSP-46** is a multi-surface cleaner, deodorizer, and disinfectant. Use on windows, mirrors, Plexiglas, Lexan, and other glass surfaces.

Use **CSP-46** on the multi-touch surfaces responsible for cross-contamination.

Use **CSP-46** on tables, chairs, bathroom bowls, basins, countertops, bed rails, door knobs and handles, glass surfaces including windows and mirrors.

**CSP-46** combines streak-free cleaning and hospital disinfectancy with no compromise in performance.

**CSP-46** is a glass cleaner, all-purpose cleaner, and disinfectant all in one.

**CSP-46** kills *Staphylococcus aureus* and *Salmonella choleraesuis*.

**CSP-46 CONCENTRATE** is an effective fungicide against *Trichophyton mentagrophytes* (the athlete's foot fungus) when used in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities.

**CSP-46** kills germs that cause bad odors.

**CSP-46** disinfects!

**CSP-46** cleans and disinfects.

**CSP-46** cleans today's soils and disinfects today's germs.

**CSP-46** leaves a fresh clean scent.

**CSP-46** maximizes labor results by effectively controlling odors.

**CSP-46** is recommended for non-scratch cleaning of showers and tubs, shower doors and curtains, fixtures, and toilet bowls.

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**CSP-46 may be used in:**

- hospitals, nursing homes, medical and dental offices and clinics, operation rooms, isolation wards, and medical research centers.
- day care centers and nurseries.
- restaurants and bars, cafeterias, institutional kitchens, fast food operations, and food storage areas.
- supermarkets, convenience stores, retail and wholesale establishments, dressing rooms, and laundries.
- crime scenes and funeral homes.
- institutional facilities, laboratories, factories, business and office buildings, restrooms, hotels and motels, and transportation terminals.
- kitchens, bathrooms, and other household areas.
- institutions, schools and colleges, classrooms, athletic facilities and locker rooms.
- camp grounds, play grounds, and recreational facilities.
- food processing plants, dairy farms, hog farms, poultry and turkey farms and egg processing plants.
- veterinary clinics, animal life science laboratories, kennels, breeding and grooming establishments, pet animal quarters, zoos, pet shops, and other animal care facilities.
- household and automotive garages, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, and airplanes.
- all public places where cleanliness and bacterial control are vital aspects of the environmental sanitation program, and any commercial, industrial, or institutional facility where a clean and sanitary environment is important.

**CSP-46 may be used on washable hard nonporous surfaces including:**

- non-food contact counter tops, sinks, refrigerators, coolers, freezers, stovetops, appliances, non-food contact equipment, shelves, racks and carts.
- picnic tables and outdoor furniture.
- telephones and computers/keyboards.
- tables, chairs, desks, bedframes, walls, cabinets, doorknobs, and garbage cans.
- highchairs and baby toys.
- drinking fountains.
- shower stalls, shower doors and curtains, tubs and tiles, toilets, urinals, portable toilets, porcelain filing, and restroom fixtures.
- kennels and cages.
- windows and mirrors.
- glass, metal, stainless steel, glazed porcelain, ceramic, fiberglass, stone, granite, marble, plastic, chrome and vinyl.

**Note:** CSP-46 is safe on most washable surfaces. However, on painted surfaces and wall coverings test a small area before use. If applied to aluminum (or copper or brass), wipe dry immediately.

**Note:** Repeated use on copper or brass may discolor these surfaces.

**Note:** Do not use on copper or brass as repeated use can discolor these surfaces.

**CSP-46 is a Hospital Use Disinfectant, is Bactericidal according to the AOAC Germicidal Spray Products Test Method, Virucidal\* according to the virucidal qualification, Fungicidal according to the AOAC fungicidal test, modified in the presence of 5% organic serum and 400 ppm hard water against the following bacteria, viruses and fungi:**

*Pseudomonas aeruginosa*  
*Staphylococcus aureus*  
*Salmonella choleraesuis*  
 Methicillin-resistant *Staphylococcus aureus* (MRSA)  
 Vancomycin-resistant *Enterococcus faecalis* (VRE)  
*Pseudomonas cepacia*  
*Shigella dysenteriae*  
*Serratia marcescens*  
*Staphylococcus epidermidis*  
*Streptococcus pyogenes*  
*Klebsiella pneumoniae*  
*E. coli* 0157:H7 (pathogenic *E. coli*)  
*Enterobacter aerogenes*  
*Proteus vulgaris*

*Trichophyton mentagrophytes*

\* Influenza A<sub>2</sub> Hong Kong  
 Respiratory Syncytial Virus (RSV)  
 Vaccinia  
 Herpes Simplex Type 1  
 Herpes Simplex Type 2  
 HIV-1 (AIDS virus)

**CSP-46 is a sanitizer for non-food contact surfaces in the presence of 400 ppm hard water plus 5% organic serum in 5 minutes against:**

*Klebsiella pneumoniae*  
*Staphylococcus aureus*

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 with COMMENTS  
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6836-245

### Directions for Use:

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

(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, whether into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection).

### Ready to Use Solution

No dilution necessary.

### Disinfection Directions:

Spray CSP-46 with this product's coarse spray device to disinfect hard, nonporous surfaces. Clean surfaces with CSP-46 prior to disinfecting heavily soiled areas. Treated surfaces must remain wet for 10 minutes. Wipe with a paper towel or lint-free cloth.

### Sanitizing Non-Food Contact Surface Directions:

Spray CSP-46 with this product's coarse spray device to sanitize hard porous and nonporous environmental surfaces. Treated surfaces must remain wet for 5 minutes. Wipe with a paper towel or lint-free cloth.

### Cleaning Directions:

Spray CSP-46 on surface to be cleaned. Wipe dirt away with a paper towel or lint-free cloth.

### Glass Cleaning Directions:

Spray CSP-46 on windows, mirrors and glass surfaces. Wipe with a paper towel or lint-free cloth. Spray 6-8 inches from surface, rub with a paper towel or lint-free cloth.

### Deodorizing Directions:

Spray CSP-46 to deodorize hard nonporous surfaces.

### (Refill:

- Refill 32 oz. sprayer size from this convenient refill container.
- Use only in CSP-46 spray bottle.
- Do not dilute)

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\*Kills HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health-care settings or other settings in which there is an expected likelihood of soiling on inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

### "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS"

**PERSONAL PROTECTION:** Clean-up should always be done wearing protective latex gloves, gown, mask and eye protection.  
**CLEANING PROCEDURE:** Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of CSP-46.

**CONTACT TIME:** Leave surface wet for 1 minute. Use a 10 minute contact time for all other bacteria, viruses and fungi listed on this label.

**DISPOSAL OF INFECTIOUS MATERIALS:** Blood, body fluids, cleaning materials and other clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.