

PM31 6836-244

4/5/98

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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 Concentrate - Additional Organisms & Label Claims
EPA Registration No. 6836-244
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 Concentrate 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 Concentrate kills germs and bacteria and cuts grease and grime" to read "CSP-46 Concentrate kills many germs and bacteria and cuts grease and grime."
4. On the bottom right panel of page two, revise "CSP-46 Concentrate kills germs that cause bad odors" to read "CSP-46 Concentrate kills many germs that cause bad odors."
5. 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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6. 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."

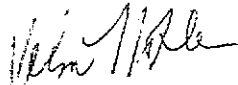
7. On page four, in the Directions for Use, under the "Sanitizing Non-Food Contact Surface Directions" section of the label, delete "porous" since the submitted and accepted sanitizing data for this product only supports a usage for hard, nonporous surfaces.

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)

Enclosures

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Danger. Corrosive. Causes irreversible eye damage. Causes skin burns. Do not get in eyes, on skin or on clothing. Wear goggles or face shield, protective clothing and rubber gloves when handling concentrate. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

(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: 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 the hazardous waste representative at the nearest EPA Regional Office for guidance.

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 empty container. Wrap and put in trash.

CSP-46 CONCENTRATE

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 (C₁₄-60%, C₁₆-30%, C₁₂-5%, C₁₈-5%)
Dimethyl Benzyl Ammonium Chloride . . . 0.5%
n-Alkyl (C₁₂-68%, C₁₄-32%) Dimethyl
Ethylbenzyl Ammonium Chloride 0.5%
Inert Ingredients: 99.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

**SEE SIDE PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS**

EPA Reg. No. 6836-244
EPA Est. No.

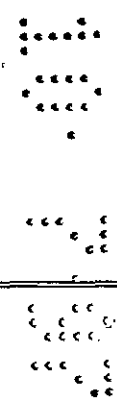
Net Contents:

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.

6836-244



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PAGE 2, 09/29/97. CSP 46 CONCENTRATE

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under FIFRA Reg. No. 6830-244

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CSP-46 CONCENTRATE disinfects and deodorizes.

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 CONCENTRATE cleans tough dirt while leaving a fresh, clean, scent.

CSP-46 CONCENTRATE kills germs that cause bad odors.

CSP-46 CONCENTRATE cleans and deodorizes.

CSP-46 CONCENTRATE cuts grease and deodorizes.

CSP-46 CONCENTRATE disinfects!

CSP-46 CONCENTRATE cuts grease, grime and deodorizes.

CSP-46 CONCENTRATE cleans and disinfects.

For use in households.

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

Contains no phosphorous, butyl cellosolve or butoxyethanol.

CSP-46 CONCENTRATE leaves a fresh clean scent.

Contains no ammonia.

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

Contains biodegradable cleaning agents.

Contains cleaning agents, perfume, dye and water.

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

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CSP-46 CONCENTRATE 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 CONCENTRATE 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 CONCENTRATE** 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 CONCENTRATE 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 A₂ Hong Kong
- Respiratory Syncytial Virus (RSV)
- Vaccinia
- Herpes Simplex Type 1
- Herpes Simplex Type 2
- HIV-1 (AIDS virus)

CSP-46 CONCENTRATE 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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection).

Preparation of use-solution:

Dilute 1 part of CSP-46 CONCENTRATE per 9 parts water (3.2 ounces per 32 oz. spray bottle). Mix thoroughly until dilution becomes a clear, light (blue) (red) (green) (yellow) (orange) liquid. Transfer diluted product to a coarse spray bottle. (1 gallon of CSP-46 CONCENTRATE makes 10 gallons of diluted product).

Disinfectant Directions:

Spray CSP-46 CONCENTRATE to disinfect hard, nonporous surfaces. Clean surfaces with CSP-46 CONCENTRATE 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 CONCENTRATE 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 CONCENTRATE on surface to be cleaned. Wipe dirt away with a paper towel or lint-free cloth.

Glass Cleaning Directions:

Spray CSP-46 CONCENTRATE 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 CONCENTRATE to deodorize hard, nonporous surfaces.

*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, gowns, masks 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 CONCENTRATE.

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.

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