

NOV 17 2003

Mr. Robert Sloan
Sr. Regulatory Services Associate
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

Subject: **CSP-46 Concentrate**
EPA Registration Number 6836-244
Letter Dated October 02, 2003
EPA Received Date October 05, 2003

Dear Mr. Sloan:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comment.

Proposed Amendment:

- revise labeling per EPA letter dated 8/04/03

General Comments:

1. Page 2: Delete the 6th claim "germs" and change to "bacteria".

A stamped copy of the labeling accepted with conditions 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 Drusilla Copeland on (703) 308-6224.

Sincerely,



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

CONCURRENCES

SYMBOL	Enclosure Stamped Label						
SURNAME							
DATE							

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Danger. Corrosive. Causes irreversible eye damage and skin burns. Harmful if absorbed through skin. 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.

FIRST AID

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF SWALLOWED: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. 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.

PHYSICAL OR CHEMICAL HAZARDS

Do not use or store near heat or open flame.

CSP-46 CONCENTRATE

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

Active Ingredients:

n-Alkyl (C ₁₄ -60%, C ₁₆ -30%, C ₁₂ -5%, C ₁₈ -5%)	
Dimethyl Benzyl Ammonium Chloride0.5%
n-Alkyl (C ₁₂ -68%%, C ₁₄ -32%) Dimethyl	
Ethylbenzyl Ammonium Chloride0.5%
Other Ingredients <u>99.0%</u>
Total100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See [left] [side] [right] [back] panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-244

EPA Est. No. (as indicated on container)

Net Contents: (as indicated on container)

Manufactured by:
Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 17 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 6836-244

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

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 is recommended for use in hospitals, medical and dental offices, nursing homes, public rest rooms, institutions, schools, colleges, athletic facilities, kitchens, restaurants and bars, airports, transportation terminals, hotels and motels.

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

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

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

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

CSP-46 CONCENTRATE disinfects and deodorizes.

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

CSP-46 CONCENTRATE cleans and deodorizes.

CSP-46 CONCENTRATE cuts grease and deodorizes.

CSP-46 CONCENTRATE cuts grease, grime and deodorizes.

For use in households.

Contains no phosphate, butyl cellosolve or butoxyethanol.

Contains no ammonia.

Contains cleaning agents, perfume, dye and water.

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

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

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

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

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

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.

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

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

CSP-46 CONCENTRATE 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 CONCENTRATE kills many bacteria that cause bad odors.

CSP-46 CONCENTRATE disinfects!

CSP-46 CONCENTRATE cleans and disinfects.

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

CSP-46 CONCENTRATE leaves a fresh clean scent.

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

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

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, and fast food operations.
- supermarkets, convenience stores, retail and wholesale establishments and dressing rooms.
- 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.
- household and automotive garages.
- 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 non-porous surfaces including:

- non-food contact counter tops, sinks, exterior surfaces of 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
- drinking fountains.
- shower stalls, shower doors and curtains, tubs and tiles, Glazed porcelain tiling,
- and restroom fixtures.
- windows and mirrors.
- glass, metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, plastic, chrome and vinyl.
- fiberglass sinks, tubs and showers

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.

Hard Surface Cautionary Statement

[May discolor aluminum, copper and brass]
[Repeated use may discolor aluminum, copper and brass].
[Prolonged exposure may discolor aluminum, copper and brass].

CSP-46 CONCENTRATE is a Hospital Use Disinfectant, is Bactericidal according to the AOAC Germicidal Spray Products Test Method, Virucidal on hard, non-porous inanimate surfaces 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:

[Bacteria:]

Pseudomonas aeruginosa [Pseudomonas]
Staphylococcus aureus [Staph]
Salmonella choleraesuis [Salmonella]

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

**[Viruses:]*

Influenza A₂ Hong Kong (Influenza)
Respiratory Syncytial Virus (RSV)
Vaccinia (Pox Virus)
Herpes Simplex Type 1 [Herpes]
Herpes Simplex Type 2 [Herpes]
HIV-1 [AIDS virus]

[Fungi:]

Trichophyton mentagrophytes [Athlete's Foot Fungus]

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

(ALTERNATE LANGUAGE FOR DILUTION CENTER)

ATTACHING THIS PRODUCT TO THE P&G DILUTION CENTER: Remove white shipping cap. DO NOT REMOVE LIGHT-BLUE PLUG FROM BOTTLE THROAT! Screw on light blue dispensing cap from dilution center product tube. Push down while twisting.

Concentrated Product- Dilute before using
[1 gallon makes 10 gallons of diluted product]

Directions for Use:

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

(Note for reviewer: For labels that list medical premises and metal and/or stainless steel surfaces, one of the following statements must be used:)

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.

(or)

This product is not for use on medical device surfaces.

Preparing Disinfecting Solution:

(Note to reviewer: Alternate heading :)

(Preparation of Use dilution :)

[Mix] [Dilute] 1 part 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. [1 gallon of CSP-46 CONCENTRATE makes 10 gallons of diluted product]. [Dilute 1 part CSP-46 CONCENTRATE per 9 parts water into a spray bottle using the dilution center. Use only a coarse spray bottle.]

To Disinfect:

For heavily soiled areas, a preliminary cleaning is required. Spray 6-8 inches from hard, non-porous surfaces. Thoroughly wet surfaces with disinfecting solution for 10 minutes. Wipe with a paper towel, lint-free cloth, or allow to air dry.

Rinse all surfaces that come in contact with food such as counters, tables and stovetops with potable water before reuse. Do not use on utensils, glasses or dishes as a disinfectant.

General Cleaning Directions:

Apply to hard, non-porous and glass cleaning surfaces by coarse sprayer, sponge or cloth. Do not breathe spray mist. For non-disinfecting light cleaning, mix up to 19 parts water to 1 part concentrate.

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.

Directions for mixing/proportioning product into a spray bottle:

Preparing disinfecting solution for the spray bottle:

Fill with water to the top of the label.

Fill with water to the line marked on the bottle.

Add three ounces of concentrate [3 pumps]

Fill with water -----> [This arrow will point to a piece on an icon of a bottle.]

Add 3 ounces [3 pumps] concentrate -----> [This arrow will point to a piece on an icon of a bottle.]

Gently shake to mix.

Deodorizing Directions:

Spray CSP-46 CONCENTRATE to deodorize hard nonporous surfaces.

Sanitizing Non-Food Contact Surface Directions:

Spray CSP-46 CONCENTRATE to sanitize hard, non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes. Wipe dirt away with a paper towel or lint-free cloth.

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***KILLS HIV ON PRECLEANED 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 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.

(Note to reviewer: If container is one gallon or less, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

Do not reuse empty container. Wrap and put in trash or recycle.

(Note to reviewer: If container is greater than one gallon, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

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

Pesticide Storage:

Do not store on side. Avoid creasing or impacting of side walls.

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:

(Plastic Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

(Metal Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.