

6836-245

12-11-2003

1/9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 11 2003

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

Subject: **CSP-46**
EPA Registration Number 6836-245
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.

Proposed Amendment:

- revise labeling per EPA letter dated 8/14/03

General Comments:

1. Under Direction for Use add statement "Do not use to clean, sanitize, disinfect or deodorize utensils, glassware or cookware".
2. Under Claims - Non-FIFRA:
 - a. Revise the 10th statement by deleting the word "All" replace with "multi" purpose (cleaner) (spray)."
 - b. Revise the 28th statement adding the words "exterior surfaces" of (microwaves) and exterior surfaces of (appliances).
 - c. Revised the 31st the statement by deleting the phase "and most everything in it"
 - d. Revise the 34th statement by deleting word "every" and add most "hard nonporous " surface".
 - e. Revise the 38th statement by deleting the phase "throughout your life".

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

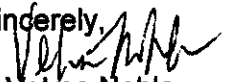
2/9

3. Under Claims - FIFRA :

- a. Revise the 16th phrase by deleting the word "All" replace with "Multi Purpose Cleaner) (spray)"
 - b. Revise the 21st statement by adding the word "Nonporous Surface and glass (cleaner) (spray)"
 - c. Revise the 22nd statement by deleting the word "all" replace with "Multi Purpose (cleaner) (spray)"
4. On page 4 in the 31st statement delete the word "germs" replace with "odor causing bacteria"
5. On page 5 in the bulleted section of the right column add "exterior surfaces of " to appliances, add "glazed" to tiles and add "glazed" to porcelain.

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)

Enclosure Stamped Label

3/9

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Causes eye irritation. Avoid contact with eyes or clothing. 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.

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 reviewer: If the container size is 5 gallons or greater, the following Environmental Hazards statements will be used:)

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 use or store near heat or open flame.

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 ₁₄ -60%, C ₁₆ -30%, C ₁₂ -5%, C ₁₈ -5%) Dimethyl Benzyl Ammonium Chloride	0.05%
n-Alkyl (C ₁₂ -68%, C ₁₄ -32%) Dimethyl Ethylbenzyl Ammonium Chloride.....	0.05%
Other Ingredients.....	99.90%
Total:.....	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See (left) (side) (right) (back) panel for Precautionary Statements and First Aid

EPA Reg. No. 6836-245
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

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4/9

Note to reviewer: The following is considered optional marketing language:

(CLAIMS – NON-FIFRA)

(Note to reviewer: The following claims containing "New" may only be used for a period of six months after EPA's approval of a revised or alternate formula, beginning when the product is first sold or distributed.)

New

New Formula

New Streak-free shine formula

Streak-Free [or Streak Free]

Streak-free Shine

Streak-free Formula

Multi-Surface [Cleaner] [Spray]

Multi-Shine

Multi-Purpose [Spray]

All Purpose [Cleaner] [Spray]

Gives Streak-free shine while it cleans

Sparkling streak-free shine

No dulling residue

No streaking or filming

Leaves no smeary residue

No smeary residue

No residue

No filming

No streaking

Fresh Clean Scent

Fresh Scent

Leaves a Fresh [Clean] Scent

Leaves your house smelling [clean] [and fresh]

Cuts Grease

Cuts Tough Grease

Cuts [tough] [grease] [and grime]

Wipes out tough [grease] [and grime]

Cleans to a streak-free shine [glass], [windows], [mirrors], [faucets], [appliances] [stainless steel], [stove tops] [glass furniture], [oven fronts], [microwaves], [and shiny surfaces]

Cleans [kitchen] [household] surfaces to a streak-free shine [even glass]

Cleans your whole house and [most] everything in it [to a streak-free shine]

Cleans and deodorizes your whole house [and] [most] everything in it

Cleans [kitchens], [bathrooms], [glass], [windows] [mirrors], [appliances] [household surfaces] [and shiny surfaces]

Cleans [kitchens], [bathrooms], [glass], [windows], [mirrors] [shiny surfaces], [and household surfaces] to a streak free shine

Cleans To a Sparkling Shine [Most Everywhere], [Most Every Surface], [Most Every Hard Surface], [Most Surfaces], [Most Shiny Surfaces]

No grease [and No Streaks]

Cuts [grease] [and grime], while leaving a streak- free shine

One product to [clean] [and shine] just about any surface

One product to [thoroughly] clean surfaces [throughout the kitchen] [throughout the house] [throughout your bathroom] [throughout your life]

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5/9

No harsh odor
 No overpowering chemical odor
 Leaves your house smelling good
 Leaves your house smelling clean and fresh
 Easy to Use
 Makes life easier
 Easier to clean with one solution [for the whole house] [for multi surfaces]
 The cleaning solution for your busy life
 Makes cleaning easier

(CLAIMS – FIFRA)

Cuts grease, [disinfects], [deodorizes], [sanitizes], and [shines]
 Cuts grease, [kills germs], (cleans glass), and shines (surfaces)
 Cuts grease [and grime], [kills germs], and [shines]
 Cleans and disinfects hard non-porous household surfaces
 Cleans [and shines], [and disinfects] [hard non-porous household surfaces]
 Cleans, disinfects [hard non porous surfaces], and shines [throughout the house]
 Cleans, disinfects [hard non porous surfaces], and shines quickly and easily
 [Effectively] cleans [even grease] [dirt] [and grime], [windows], [mirrors], [shiny surfaces], [and kills germs]
 Cleans, [and] disinfects [hard non porous surfaces], and shines your [shiny] surfaces, [including glass], [including windows], [including mirrors]
 Cleans and disinfects [hard non porous surfaces], [deodorizing], [sanitizing] while leaving a streak-free shine
 Combines a grease cutting formula with antibacterial ingredients [to clean] and [shine]
 Combines antibacterial cleaning with steak-free shine
 Disinfects [as it cleans] [and shines]

Antibacterial [Cleaner] [Spray]
 New Antibacterial
 Antibacterial All Purpose [Cleaner] [Spray]
 Antibacterial Multi-Surface [Cleaner] [Spray]
 Antibacterial Multi-Surface and Glass [Cleaner] [Spray]
 Antibacterial Glass & Surface [Cleaner] [Spray]
 Antibacterial Surface and Glass [Cleaner] [Spray]
 Antibacterial Hard Surface and Glass [Cleaner] [Spray]
 3 in 1 Antibacterial All Purpose [Cleaner] [Spray]
 Antibacterial Multi-surface All Purpose [Cleaner] [Spray]
 Multi-Bacterial
 Multi-Surface Disinfecting [hard non porous surfaces]

Disinfectant
 Disinfects
 Kills Germs
 Kills 99.9% of Germs
 Kills more than 99.9% of household germs
 Sanitizes
 Sanitizing
 Sanitization

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6/9

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, public rest rooms, institutions, schools, colleges, athletic facilities, 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 cleaning agents, perfume, dye and water.

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, 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 soils and disinfects germs.

CSP-46 leaves a fresh clean scent.

CSP-46 maximizes labor results by effectively controlling odors.

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7/9

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

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.
- 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.
- 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, refrigerator exteriors, coolers, freezers, stovetops, appliances, non-food contact equipment, shelves, racks and carts.
- picnic tables and outdoor furniture.
- telephones and computers/keyboards.
- tables, chairs, desks, bed frames, walls, cabinets, doorknobs, and garbage cans.
- highchairs and baby toys.
- drinking fountains.
- shower stalls, shower doors and curtains, tubs and tiles,
- fiberglass sinks, tubs and showers
- porcelain tiling and restroom fixtures.
- kennels and cages.
- windows and mirrors.
- glass, metal, stainless steel, glazed porcelain, glazed ceramic, sealed stone, sealed granite, sealed 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, 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.

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8/9

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:

(Bacteria:)

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

E. coli O157:H7 [*pathogenic E. coli*]
Enterobacter aerogenes
Klebsiella pneumoniae
Methicillin-resistant Staphylococcus aureus [*MRSA*]
Vancomycin-resistant Enterococcus faecalis [*VRE*]
Proteus vulgaris
Pseudomonas cepacia
Shigella dysenteriae
Serratia marcescens
Staphylococcus epidermidis
Streptococcus pyogenes

**(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 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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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, 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.

(or)

This product is not for use on medical device surfaces.

[Cleaning] [Surface] [and] [Glass] Directions:

[Turn] [Rotate] nozzle to "On" [position]
[Hold] [Spray] 6-8 inches from surface.
Wipe with a [dry] paper towel or [lint free] cloth [to a streak free shine.] [No rinsing necessary.]

Or

(Cleaning) (Surface) (Glass) (Directions) (:)

(Turn) (Rotate) nozzle to "On" (position)
(Spray) (and) wipe with a (dry) paper towel or lint free cloth (to a streak free shine) (no rinsing necessary)

To [(Disinfect) (/) [(Sanitize) (/) [(Deodorize):

For heavily soiled areas, a precleaning is required.
For hard nonporous surfaces, spray until thoroughly wet.

To Sanitize: Let stand 5 minutes before wiping.

To disinfect: Let stand for 10 minutes before wiping.

Note to reviewer: These Use Sites may be depicted by Pictures:

[Bathroom], [Glass furniture], [Kitchen*], [Car window], [Window], [Mirror], [Appliances*], [Outdoor grill], [Patio Furniture], [Floor], [Garbage can], [Pet area], [Wall], [Glass Surfaces], [Other Surfaces]

*A rinse is required for surfaces in direct contact with food.

[Refill:

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

9/9

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BOOD / 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**.

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 container except with CSP-46. If not refilling, discard 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.

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