

6836-244

11/15/2002

1/6

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Patricia A. Moriarty  
Sr. Regulatory Associate  
Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410

NOV 15 2002

Subject: Notification per PR Notice 98-10  
Lonza Formulation S -21  
EPA Reg. No. 6836-244  
Application dated: October 7, 2002  
Receipt Date: October 18, 2002

Dear Ms. Patricia A. Moriarty,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification**


- Notification to correct the following grammatical errors on the 4-7-99 EPA stamped label and Notification dated 11/10/99.
  - Insert "use or " in the PHYSICAL OR CHEMICAL HAZARDS.
  - Change "phosphorous" to "phosphate" on Page 2 (marketing language)
  - Change "closed loop dilution center" to "P&G Dilution Center" Page 4, top left column

**General Comments**

Based on a review of the material submitted, the following comments apply:

This notification application is acceptable and a copy has been made a part of the records for this file.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6233.

Sincerely,  
  
Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobial Division (7510C)

CONCURRENCES							
SYMBOL	7510(C)						
SURNAME	A. Peters						
DATE	11/14/02						



United States  
Environmental Protection Agency  
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number  
283671

Application for Pesticide - Section I

1. Company/Product Number 6836-244	2. EPA Product Manager VELMA NOBLE	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LONZA FORMULATION S-21	PM# PM-31	
5. Name and Address of Applicant (Include ZIP Code) LONZA INC. 17-17 ROUTE 208 FAIR LAWN, NJ 07410 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)  
LABEL  
Notification: Correct grammatical errors and change "Closed loop" to "P&G Dilution Center"

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name PATRICIA A. MORIARTY	Title SR. REGULATORY ASSOCIATE	Telephone No. (Include Area Code) 201-794-2701
2. Signature 		6. Date Application Received (Stamped)
3. Title SR. REGULATORY ASSOCIATE		
4. Typed Name PATRICIA A. MORIARTY		5. Date October 7, 2002
<p><b>Certification</b></p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		

**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 statement).

**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.

(If the container size is greater than 1 gallon, use the following Storage and Disposal statement).

**STORAGE OR 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 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	0.5%
n-Alkyl (C <sub>12</sub> -68%, C <sub>14</sub> -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. 6836-IL-1

Net Contents:

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

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, 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** 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 many germs and 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 biodegradable cleaning agents.

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, non-porous 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 germs 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, fixtures, and toilet bowls.

**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 non-porous 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
- 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, 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.

**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:

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Vancomycin-resistant Enterococcus faecalis(VRE)
- Pseudomonas cepacia
- Shigella dysenteriae
- Serratia marsecens
- 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 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.

**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).

**Preparing Disinfecting Solution:**

(Mix) 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:**

Clean surfaces prior to disinfecting heavily soiled areas. Thoroughly wet surfaces with disinfecting solution 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, non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes. Wipe dirt away with a paper towel or lint-free cloth.

**General Cleaning Directions:**

Apply to hard, non-porous and glass cleaning surfaces by coarse sprayer, sponge or cloth. Do not breath 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 non-porous 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.