

JAN 11 1999

Lonza Inc.  
17-17 Route 208  
Fair Lawn, NJ 07410-2821

ATTENTION: Ruth Trager

SUBJECT: Formulation HWS-256  
EPA Registration Number 47371-129  
Your Amendment Dated: October 20, 1998

This is to acknowledge receipt of your amendment to revise the labeling for this product. This amendment is acceptable subject to the comments listed below.

The provided information on "Chemia 1117R Spartan Fragrance" is still in review. Thus your Confidential Statements of Formula for the Alternate Formulations dated 7/9/98 and the Basic Formulation dated 12/23/97 cannot be accepted at this time.

As per the Agency letter of September 30, 1998 the following revision must be made to the "Pesticide Disposal" statement in order to comply with PR Notice 83-3. Revise the "Pesticide Disposal" statement to read exactly as it did on the stamped accepted label of 10/15/96 by using the following statements: *"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."*

On page two of the label, move the heading **"Farm Premises, Livestock, Poultry & Turkey House Disinfectant"** so that it is in the second column of this page and immediately proceeds the specific directions for these types of premises.

CONCURRENCES							
SYMBOL	7510C						
SURNAME	S. J. Jones						
DATE	1/7/99						

EPA Form 1320-1A (1/90)

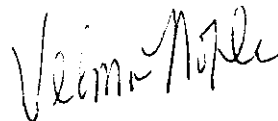
Printed on Recycled Paper

OFFICIAL FILE COPY

A stamped copy of the label is enclosed for your records. Please submit one copy of the final printed label.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure  
7510C:T.Lantz:1/6/99:47371-129b

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DILUTION: 1:256  
(630 ppm quat)

1/2 OUNCE PER GALLON OF WATER  
1 OUNCE PER 2 GALLONS OF WATER  
2 OUNCES PER 4 GALLONS OF WATER  
2 1/2 OUNCES PER 5 GALLONS OF WATER  
4 OUNCES PER 8 GALLONS OF WATER

#### 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, 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 pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

#### GENERAL USE DIRECTIONS

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, federally inspected meat and poultry establishments, equine farms, tack shops, pet shops, airports, kennels, hotels, motels, poultry farms, turkey farms, dairy farms, hog farms, breeding establishments, grooming establishments, funeral homes, and households. Disinfects, cleans, and deodorizes floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.), and other hard, nonporous surfaces.

**APPLICATION:** Remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 1/2 ounce of the concentrate per gallon of water. The solution can be applied with a cloth, mop, sponge, or coarse spray, or soaking. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. Rinsing of floors is not necessary unless they are to be waxed or polished.

Food contact surfaces must be thoroughly rinsed with potable water. Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

**USDA:** For use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas. All surfaces must be thoroughly rinsed with potable water.

**USDA:** For use in federally inspected meat and poultry plants as a floor and wall cleaner for use in all departments. Food products and packaging material must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

**USDA:** For use in federally inspected meat and poultry plants as a disinfectant agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

**TOILET BOWLS:** Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first remove or expel over the inner trap the residual bowl water. Pour in three ounces of the diluted solution. Swab the bowl completely using a scrub brush or mop, making sure to get under rim. Let stand for 10 minutes or overnight, then flush.

**MILDEWSTATIC INSTRUCTIONS:** Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply solution (1/2 ounce per gallon of water) with a cloth, mop, sponge, or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

## FORMULATION HWS-256/

### Formulacion HWS-256

#### ONE-STEP,

#### GERMICIDAL DETERGENT AND DEODORANT

Disinfectant Pseudomonacidal Staphylocidal Salmonellacidal  
Bactericidal Fungicidal Mildeustatic \*Virucidal

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO<sub>3</sub>) in the presence of a moderate amount of soil (5% organic serum) according to the AOAC Use-dilution Test. Disinfects, cleans, and deodorizes in one labor-saving step.

Effective against the following pathogens:

Pseudomonas aeruginosa <sup>1</sup>	*Adenovirus type 4
Staphylococcus aureus <sup>1</sup>	*Avian polyomavirus
Salmonella choleraesuis	*Canine distemper
Acinetobacter calcoaceticus	*Feline leukemia
Bordetella bronchiseptica	*Feline picornavirus
Chlamydia psittaci	*Herpes simplex type 1
Enterobacter aerogenes	*Herpes simplex type 2
Enterobacter cloacae	*HIV-1 (AIDS virus)
Escherichia coli <sup>1</sup>	*Infectious bovine rhinotracheitis
Fusobacterium necrophorum	*Infectious bronchitis (Avian IBV)
Klebsiella pneumoniae <sup>1</sup>	*Influenza A/Hong Kong
Legionella pneumophila	*Pseudorabies
Listeria monocytogenes	*Rabies
Pasteurella multocida	*Rubella (German Measles)
Proteus mirabilis	*Transmissible gastroenteritis virus (TGE)
Proteus vulgaris	*Vaccinia
Salmonella enteritidis	*Respiratory Syncytial virus (RSV)
Salmonella typhi	
Salmonella typhimurium	
Serratia marcescens	
Shigella flexneri	
Shigella sonnei	
Staphylococcus aureus, (methicillin resistant)	
Staphylococcus epidermidis <sup>2</sup>	Aspergillus niger
Streptococcus faecalis <sup>1</sup>	Candida albicans
Streptococcus pyogenes	Trichophyton mentagrophytes
Enterococcus faecalis (Vancomycin Resistant)	
	<sup>1</sup> ATCC & antibiotic-resistant strain
	<sup>2</sup> antibiotic-resistant strain only

#### ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride.....	9.70%
n-Alkyl (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C <sub>16</sub> 10%) dimethyl benzyl ammonium chloride.....	6.47%
INERT INGREDIENTS:.....	83.83%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

(See side panel for additional precautionary and practical treatment statements)

EPA Reg. No. 47371-129 EPA Est. No. \_\_\_\_\_  
NET CONTENTS \_\_\_\_\_

H&S CHEMICALS DIVISION

c/o LONZA INC., 17-17 ROUTE 208, FAIR LAWN, NJ 07410

#### PRECAUTIONARY STATEMENTS

##### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER. CORROSIVE.** Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. When handling product, protect eyes by wearing goggles or face shield and protect skin by wearing rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

##### STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. If swallowed, call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. 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. Measures against circulatory shock, respiratory depression and convulsion may be needed.

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

##### ENVIRONMENTAL HAZARD

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters 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.

(If container size is one gallon or less, use the following Storage and Disposal statements:)

##### STORAGE AND DISPOSAL

Keep product under locked storage, inaccessible to small children. Do not reuse empty container. Rinse thoroughly, securely wrap empty container in several layers of newspaper, and discard in trash.

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

##### STORAGE AND DISPOSAL

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

##### PESTICIDE STORAGE

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

##### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

##### 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, burn. If burned, stay out of smoke.

(Fiber Drums With Liner:) Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(Metal Container:)

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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

JAN 11 1999

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

(October 20, 1998) (EPA - M)

47371-129

**\*KILLS HIV-1 (AIDS VIRUS) 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 of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects likely to be soiled with blood/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 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures.

**Cleaning Procedures:** Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant.

**Contact Time:** HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (room temperature). Use a 10-minute contact time for other viruses, fungi, and bacteria listed.

**Disposal of Infectious Materials:** Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.  
**CLEANSING OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS:**

This product removes body secretions, soil, and blood, along with their accompanying malodor, from the surfaces and orifices of human remains. Using a sponge or washcloth, bathe the entire body with a solution of 1/2 ounce per gallon of water. A soft handbrush may be employed on surfaces other than the face. Prepare a fresh solution for each remains or when solution becomes visibly dirty or diluted.

**FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT**

DILUTION: 1:256 1/2 OUNCE PER GALLON OF WATER

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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47371-129

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