

PM 31

47371-130 1-11-99
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

lot 3

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

JAN 11 1999

ATTENTION: Ruth Trager

SUBJECT: Formulation HWS-128
EPA Registration Number 47371-130
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 and the Basic Formulation, each of which are dated 12/23/97, cannot be accepted at this time.

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

CONCURRENCES

SYMBOL	7510C: T. Lantz: 1/7/99: 47371-130b						
SURNAME	7510C						
DATE	1/7/99						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

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

DILUTION: 1:128
(630 ppm quat)

1 OUNCE PER GALLON 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 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, non-porous surfaces such as walls, floors, and table tops. Apply solution (1 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.

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.

4737H-130

Formulation HWS-128 (October 20, 1998) (EPA - M)

FORMULATION HWS-128

Formulacion HWS-128

ONE-STEP,

GERMICIDAL DETERGENT AND DEODORANT

Disinfectant Pseudomonacidal Staphylocidal Salmonellacidal
Bactericidal Fungicidal Mildewstatic *Virucidal

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO₃) 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*¹
*Staphylococcus aureus*¹
Salmonella choleraesuis
Acinetobacter calcoaceticus
Bordetella bronchiseptica
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
*Escherichia coli*¹
Fusobacterium necrophorum
*Klebsiella pneumoniae*¹
Legionella pneumophila
Listeria monocytogenes
Pasteurella multocida
Proteus mirabilis
Proteus vulgaris
Salmonella enteritidis
Salmonella typhi
Salmonella typhimurium
Serratia marcescens
Shigella flexneri
Shigella sonnei
Staphylococcus aureus,
(methicillin resistant)
*Staphylococcus epidermidis*²
*Streptococcus faecalis*¹
Streptococcus pyogenes
Enterococcus faecalis
(Vancomycin Resistant)

*Adenovirus type 4
*Avian polyomavirus
*Canine distemper
*Feline leukemia
*Feline picornavirus
*Herpes simplex type 1
*Herpes simplex type 2
*HIV-1 (AIDS virus)
*Infectious bovine rhinotracheitis
*Infectious bronchitis (Avian IBV)
*Influenza A/Hong Kong
*Pseudorabies
*Rabies
*Rubella (German Measles)
*Transmissible gastroenteritis virus (TGE)
*Vaccinia
*Respiratory Syncytial virus (RSV)

Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

¹ ATCC & antibiotic-resistant strain
² antibiotic-resistant strain only

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride	4.85%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%)	
dimethyl benzyl ammonium chloride	3.23%
INERT INGREDIENTS:	91.92%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

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

EPA Reg. No. 47371-130

EPA Est. No. (as market on container)

NET CONTENTS: (as market on container)

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

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 incinerate, 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.

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*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 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.

ACCEPTED

with COMMENTS

In EPA Letter Dated:

JAN 11 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
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47371-130

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

DILUTION: 1:128 1 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.