

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

H&S Chemicals Division
c/o Lonza Inc.
17-17 Route 208
Fair Lawn, NJ 07410

SEP 17 2001

ATTENTION: Samantha Bates
Agent for Lonza

SUBJECT: Formulation HWS-128
EPA Registration Number: 47371-130
Your Amendment Dated: March 21, 2001
EPA Received Date: March 22, 2001

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) to add the organism Hepatitis B Virus and increase the active ingredients, is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

Generic Data Matrixes

You have cited at least one acceptable study for each of the required guidelines to support this use pattern. Once an acceptable study has been identified on your matrix, we do not review the status of any additional studies listed.

Please be advised that at the time of reregistration you will be required to submit chemistry data on each active ingredient in this product.

End Use Data Matrixes

In the future, when submitting product specific data matrixes which include efficacy data, identify on the matrix the specific organism which is supported by each MRID listed.

Please be advised that at the time of reregistration you will be required to submit chemistry data on this formulation.

CONCURRENCES							
SYMBOL	750C						
SURNAME	J. Lang						
DATE	9/17/01						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

The submitted Confidential Statements of Formula for the Basic and Alternates #1, 2, 4, 5, 6, 7, 8, and 9 dated March 7, 2001 and Alternate #3 dated March 8, 2001 are acceptable and have been made part of the record for this file.

2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. Revise the "First Aid" statements as follows: move the statement "Call a poison control center or doctor for treatment advice" from the "IF IN EYES" and "IF ON SKIN OR CLOTHING" statements and place this statement at the end of the "First Aid" section.

B. Immediately following this statement, place the additional statement:
"Have the product container or label with you when calling a poison control center or doctor or going for treatment."

Do not revise the "IF SWALLOWED" statement.

3. Submit two (2) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, this registration will be subject to cancellation in accordance with FIFRA sec. 6 (e). Your release for shipment of this product bearing the amended labeling constitutes acceptance of these conditions.

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: Stamped Label
7510C:T.Lantz:9/14/01:47371130q

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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.

FIRST AID

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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer: If 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 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.

FORMULATION HWS-128**ONE-STEP DISINFECTANT****GERMICIDAL DETERGENT AND DEODORANT**

Disinfectant	Pseudomonacidal
Staphylocidal	Salmonellacidal
Bactericidal	Fungicidal
Mildewstatic	*Virucidal

FLORAL / CITRUS / FRESH / CLEAN / LEMON / PINE /
MINT (scent)(fragrance)(odor)(scented)

Active Ingredients:

Didecyl dimethyl ammonium chloride	5.07%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride	3.38%
Inert Ingredients:	91.55%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN**DANGER**

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

EPA Reg. No. 47371-130

EPA Est. No. (*insert Est. No. here*)

NET CONTENTS: (*insert container size here*)

H&S CHEMICALS DIVISION
c/o LONZA INC.

17-17 ROUTE 208, FAIR LAWN, NJ 07410

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-130

A multi-purpose, neutral pH, germicidal detergent and deodorant effective in hard water up to 400 ppm (calculated as CaCO_3) 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.

Recommended for use in hospitals, nursing homes, schools, colleges, commercial and industrial institutions, office buildings, veterinary clinics, animal life science laboratories, zoos, 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 the following hard, nonporous, inanimate surfaces: floors, walls, (*non-medical*) metal surfaces, (*non-medical*) stainless steel surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.).

Recommended for use in:

- Federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, non-processing areas and/or exterior areas. All surfaces must be thoroughly rinsed with potable water.
- 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.
- 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.

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Effective against the following pathogens:

(*Bacteria*.)

*Pseudomonas aeruginosa*¹
*Staphylococcus aureus*¹
Salmonella choleraesuis

Acinetobacter calcoaceticus
Bordetella bronchiseptica
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
Enterococcus faecalis-Vancomycin Resistant
*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 -(MRSA)
Staphylococcus aureus-Vancomycin Intermediate Resistant-(VISA)
*Staphylococcus epidermidis*²
*Streptococcus faecalis*¹
Streptococcus pyogenes

¹ ATCC & antibiotic-resistant strain

² antibiotic-resistant strain only

(*Viruses*.)

*Adenovirus Type 4
*Hepatitis B Virus (HBV)
*Herpes Simplex Type 1
*Herpes Simplex Type 2
*HIV-1 (AIDS virus)
*Influenza A / Hong Kong
*Respiratory Syncytial Virus (RSV)
*Rubella (German Measles)
*Vaccinia

(*Animal Viruses*.)

*Avian polyomavirus
*Canine distemper
*Feline leukemia
*Feline picornavirus
*Infectious bovine rhinotracheitis
*Infectious bronchitis (Avian IBV)
*Pseudorabies (PRV)
*Rabies
*Transmissible Gastroenteritis virus (TGE)

(*Fungi*.)

Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

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 (1 OUNCE PER GALLON OF WATER) (660 ppm quat)

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

(or)

This product is not for use on medical device surfaces.

DISINFECTION / CLEANING / DEODORIZING

DIRECTIONS: Remove heavy soil deposits from surface, then thoroughly wet surface with a use-solution of 1 oz. of the concentrate per gallon of water. The use-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. This product must not be used to clean the following food contact surfaces: utensils, glassware and dishes.

Prepare a fresh solution daily or more often if the solution becomes visibly dirty or diluted.

TOILET BOWLS: Swab bowl with brush to remove heavy soil prior to cleaning or disinfecting. Clean by applying use-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 use-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.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

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 use-solution of 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.

***KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) 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 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 I (HIV-1) (associated with AIDS) or Hepatitis B Virus (HBV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV ON 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). HBV is inactivated after a 10 minute contact time. 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.

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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 use-solution of 1 ounce per gallon of water. A soft handbrush may be employed on surfaces other than the face. Prepare fresh solution for each (cadaver) remains or when solution becomes visibly dirty or diluted.

FARM 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, then 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, trucks, 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, then rinse with potable water before reuse.

VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 1 oz. of **FORMULATION HWS-128** per gallon of water (or *equivalent dilution*) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

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

STORAGE AND DISPOSAL

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

(Note to reviewer: If container size 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

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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