

47371-130

7/17/2003

Page 187

Samantha Bates
Agent for Lonza
Lewis & Harrison
122 C St., NW Suite 740
Washington, DC 20001

JUL 17 2003

SUBJECT: Formulation HWS-128
EPA Registration Number: 47371-130
Application Dated: January 21, 2003
Receipt Date: January 22, 2003

Dear Ms. Samantha Bates:

The following amendment, submitted in connection with registration under section 3 (c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, acceptable subject to the conditions listed below.

- Addition of Hepatitis C Virus
- Other Label Revisions

Acceptable Data

The product efficacy data submitted are acceptable to support this product as noted below.

Data Requirement	Means of Support	Status
Bovine Viral Diarrhea Virus (surrogate for Hepatitis C virus)	Submitted study, MRID 45839201	Acceptable @ 1:128 in 5% serum and 400 ppm hard water for 10 minutes
Confirmatory Bovine Viral Diarrhea Virus (surrogate for Hepatitis C virus)	Submitted study, MRID 45839202	Acceptable @ 1:128 in 5% serum and 400 ppm hard water for 10 minutes

CONCURRENCES

SYMBOL	75100						
SURNAME	S. Bates						
DATE	7/17/03						

Conditions


1. As this product is classified as Toxicity I for Primary-Skin Irritation, revise the Precautionary Statements to include the following: "...When handling product, protect eyes by wearing goggles or face shield and protect skin by wearing protective gloves *and protective clothing*. Wash thoroughly..."
2. Revise page three "Disinfection/Cleaning/Deodorizing Directions" to state: "...per gallon of water. Apply with a cloth, mop...or by soaking. *For sprayer applications, use a coarse spray device. Spray 6-8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray.* Let solution remain on surface..."
3. Revise the directions for use on toilet bowls (page three) to read: "To disinfect, *first preclean to remove heavy soil, then* remove or expel over the inner trap..."
4. Revise the directions on page three for "Bactericidal Stability of Use Dilution" to list the correct name of the product as: "Formulation **HWS-128**."
5. Revise the "Citrus Canker" directions on page 4 such that they are in agreement with PR Notice 2000-5 which describes the use of mandatory language. Revise the last two statements as follows: "*Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.*"

General Comments

A stamped copy of the accepted labeling 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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

		CONCURRENCES					
SYMBOL	Enclosure: Stamped Label						
SURNAME	510C:T.Lantz:7/17/03:47371-130u						
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 protective 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.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

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.

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 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 (C₁₄ 50%, C₁₂ 40%, C₁₆ 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:

JUL 17 2003

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

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

- Concentrate (Concentrated)
- Neutral (Neutral pH)
- Disinfects (Disinfectant)
- Cleans (Cleaner)
- Deodorizes (Deodorizer)

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.

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.

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)
 *Hepatitis C Virus (HCV)
 *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.

(Note to reviewer: one of the following two statements will be used:)

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that Formulation HWS-256, when diluted in 400 ppm hard water (via use of automatic dispensing devices), remains effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* for (up to 7 days) (for up to one week) (for up to one month) (for up to 2 months) (for up to 3 months) when stored in a sealed container such as a spray bottle. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

(or)

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 3 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) AND HCV (HEPATITIS C 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) or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV OR HCV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

Personal Protection: Disposable protective 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 (77°F) (room temperature). HBV and HCV are 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.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:

Mix 1 oz. of Formulation HWS-128 per gallon of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

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.

CITRUS CANKER DISEASE CONTROL

For prevention of Citrus Canker Disease through treatment of equipment. Effective against *Xanthomonas axonopodis* pv. citri (Citrus Canker Disease) at 2000 ppm active quat. Treatments can be applied to trucks, attached trailers, and field equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other equipment taken into infested areas.

Saturate surfaces with a 1:42 use-dilution (12¼ oz. per 4 gallons of water) (or equivalent dilution) (2000 ppm active quat) for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Clothing should be thoroughly rinsed or laundered before reuse. Footwear should be rinsed before reuse.

(Note to reviewer: If the container size is one gallon or less, the following Storage and Disposal directions 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 the container size is greater than one gallon, the following Storage and Disposal directions 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.