

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

EPA Reg. Number:

47371-192

Date of Issuance:

FEB 17 2004

NOTICE OF PESTICIDE:
Registration
Reregistration

(under FIFRA, as amended)

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

Formulation HWS-32

Name and Address of Registrant (include ZIP Code):

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

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Add the phrase EPA Registration Number "EPA Reg. No. 47371-192".

Signature of Approving Official:

Handwritten signature of Velma Noble

Velma Noble
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

FEB 17 2004

CONCURRENCES

Table with columns for SYMBOL, SURNAME, and DATE, containing handwritten entries: 7510C, J. [unclear], 2/17/04

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

3. It appears that you intended to make an additional Bactericidal Stability claim for the Use-Dilution. Add the following language to your label at the bottom of page 3 "(for up to one year)." This claim is supported by your clarification of the submitted data.

4. The MRIDs for the data which was submitted with this application have been added to the Agency file of the Data Matrix for this product. Add the same to the matrix in your records and identify these studies in future submissions for this product: Chemistry: 460989-01 and 460989-02 and Efficacy, supplement: 461200-01.

5. A claim for Hantavirus is not supported for this product. The following citation has been deleted from the Agency file of the Data Matrix for this product: 45547901. Delete the same from the matrix in your records.

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

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to the release of the product for shipment. If you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure: stamped label
7510C:T.Lantz:2/13/04:47371-192

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Do not get in eyes or clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Avoid contact with the skin. Harmful if inhaled. Avoid breathing spray. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

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.

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

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.

ACCEPTED
with COMMENTS
in EPA Review District

FEB 17 2004
Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product, registered under EPA Reg. No. 47371-192

FORMULATION HWS-32

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 1.27%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
dimethyl benzyl ammonium chloride.....0.85%
Other Ingredients:.....97.88%
Total: 100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-_____
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

(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 aeruginosa¹
- Staphylococcus aureus¹
- Salmonella choleraesuis

- Acinetobacter calcoaceticus
- Bordetella bronchiseptica
- Chlamydia psittaci
- Enterobacter aerogenes
- Enterobacter cloacae
- Enterococcus faecalis-Vancomycin Resistant (VRE)
- Escherichia coli¹
- Fusobacterium necrophorum
- Klebsiella pneumoniae¹
- 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 epidermidis²
- Streptococcus faecalis¹
- 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: (1:32) 4 ounces 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 4 ounces of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse spray 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 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 or disinfect 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-32, 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 use-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 diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first preclean to remove heavy soil, then 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.

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 2 ounces 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 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 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 OF 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 all 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 4 oz. of Formulation HWS-32 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 4 ounces per gallon of water. A soft handbrush may be employed on surfaces other than the face. Use fresh solution for each (cadaver) remains or when solution becomes visibly dirty or diluted.

FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT

DILUTION: 1:32 4 ounces 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 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. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 4 oz. of FORMULATION HWS-32 per gallon of water (or equivalent dilution) for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Ventilate buildings and other closed spaces. **Thoroughly clean all surfaces that come into contact with food, including equipment used for feeding or watering, with soap or detergent and rinse with potable water before reuse.** 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 2:21 (1:10 1/2) use-dilution (12 1/8 oz. per gallon 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. **Thoroughly rinse or launder clothing before reuse. Rinse footwear before reuse.**

(Note to reviewer: If 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 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 instruction, 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.