

PM 31 47371-129 10/16
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 15 1996

H&S Chemicals Division
970 East Tipton Street
Huntington, IN 46750

Attention: Sally Hayes
Regulatory Affairs Manager

Subject: Formulation HWS-256
EPA Registration No. 47371-129

Formulation HWS-128
EPA Registration No. 47371-130

Formulation HWS-64
EPA Registration No. 47371-131

Amendments Dated March 18, 1996

The amendments referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to add disinfection claims against Enterococcus faecalis - Vancomycin Resistant on hard, nonporous inanimate surfaces in the presence of 5% fetal bovine serum and 400 ppm of synthetic hard water when used at a dilution of 1:256 (0.5 ounce/gallon) (providing 600 ppm of active quaternary) when thoroughly wetted and allowed to remain wet for a contact time of at least 10 minutes are acceptable provided that you comply with the items below.

1. Submit/cite all data required for registration/reregistration of your products under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the products for shipment.

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

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,



Marion J. Johnson
Product Manager 31
Antimicrobial Programs Branch
Registration Division (7505C)

3076
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
(600 ppm quat)

1/2 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, non-porous environmental 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. 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, non-porous surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.

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 (1/2 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/ Formulación HWS-256

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
*Canine parvovirus
*Feline leukemia
*Feline panleukopenia
*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
*Porcine parvovirus
*Pseudorabies
*Rabies
*Respiratory syncytial virus (RSV)
*Rubella (German Measles)
*Transmissible gastroenteritis virus (TGEV)
*Vaccinia

Aspergillus niger
Candida albicans
Trichophyton mentagrophytes

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

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride 9.22%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
dimethyl benzyl ammonium chloride 6.14%
INERT INGREDIENTS: 84.64%

KEEP OUT OF REACH OF CHILDREN DANGER/PELIGRO

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

EPA Reg. No. 47371-129

EPA Est. No. 47371-IN-01

NET CONTENTS

H&S CHEMICALS DIVISION

970 East Tipton Street, Huntington, IN 46750

(219) 356-7073

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, immediately drink a large quantity of water. Avoid alcohol. Get medical attention.

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

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

CORROSIVE: Causes eye damage and severe skin irritation. 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.

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 the National Pollutant Discharge Elimination System (NPDES) permit and unless 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.

STORAGE AND DISPOSAL

Keep product under locked storage, inaccessible to children. Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinseate 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.

(FOR 1 GALLON OR LESS)

Do not reuse empty container. Rinse thoroughly, securely wrap in several layers of newspaper, and discard empty container in trash.

FIBER DRUMS WITH LINERS

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 CONTAINERS

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.

FORMULATION HWS-256

*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 I (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.

[For use as package insert or hang tag or place on label.]

031296

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 15 1996

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

47371-129

5046

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(label directions for use continued)

FORMULATION HWS-256

GERMICIDAL DETERGENT

FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT

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

DIRECTIONS FOR USE

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.

[For use as package insert or hang tag or place on label.]

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(label directions for use continued)

FORMULATION HWS-256

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.

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