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47371-130

9-21-99

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 21 1999

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

ATTENTION: Ruth Trager

SUBJECT: Formulation HWS-128
EPA Registration Number 47371-130
Your Amendment Dated: March 25, 1999
EPA Received Date: March 30, 1999

The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable subject to the following comments.

Efficacy Review

Microbiological data developed by the Official Methods of the AOAC Use Dilution Test Method 15th edition (1990) (MRID 447691-01) was submitted to support 47371-129. This study supports the claims of effectiveness of 47371-130 against *Staphylococcus aureus* (VRSA) a clinical isolate with reduced resistant susceptibility to Vancomycin at a dilution of 1:128 (1.0 ounce/gallon) in the presence of 5% organic soil (fetal bovine serum) and 400 ppm synthetic hard water.

Effectiveness was demonstrated when the diluted product was applied and allowed to remain wet for an exposure time (contact time) of 10 minutes when used on hard, nonporous, inanimate surfaces in the presence of a moderate organic soil and synthetic hard water.

The Agency has no objection to the proposed designation of *Staphylococcus aureus* (HIP-5836) as a vancomycin intermediate resistant *Staphylococcus aureus* (VISA) strain. The Agency agrees that this designation is both appropriate, more correct, and consistent with the strain designation terminology being promulgated by the Centers for Disease Control.

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

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

submit such data.

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

A. Make the correction from VRSA to VISA and correctly state vancomycin intermediate resistance next to Staphylococcus aureus on the front center panel of the label.

B. The Agency has corrected the Agency Internal Use Copy of the submitted Data Matrix such that the MRID for the study submitted to support Staphylococcus aureus (VRSA) reduced resistant susceptibility to Vancomycin reads as follows: 447691-01. Make the same correction to the Data Matrix in your files.

C. Change the heading "General Use Directions" to read "Directions for Use".

D. In the first section under "General Use Directions" delete the phrase "...and other hard, nonporous surfaces." Your label may list additional surfaces, but may not include broad nonspecific statements such as the one previously mentioned. Revise this statement to read "Disinfects, cleans, and deodorizes *the following hard nonporous inanimate surfaces*: walls, floors, metal surfaces..."

E. Change the subheading "Application" to read "Disinfection".

F. On the center panel the claims "Pseudomonacidal", "Staphylocidal", "Salmonellacidal", "Bactericidal", and "Germicidal" are not allowed since this product does not kill all organisms of the genus Pseudomonas, Staphylococcus, Salmonella, all bacteria, or all germs.

G. Correct the "Ingredients Statement" by aligning the phrase "100%" such that it is directly under the inert ingredient total of 91.92%.

H. Since this product may be used in households, a disclaimer statement must be added to the label: "This product must not be used to clean the following food contact surfaces: utensils, glassware, and dishes."

I. Make the following revision to the "Precautionary Statements." Revise "For eyes, call a physician." to read "For eyes *or skin*, call a physician."

J. The "Reusable container statement" is unclear. The Agency requests that you define what is meant by the "use dilution label." Your present label does not include statements for use dilution labeling. Provide copies of this labeling for review by the Agency. Also note that the term "sanitizer" as used in this section is inappropriate for this product since it is not registered as a sanitizer. Until the Agency's concerns regarding this "use dilution label" have been resolved this section of the label must be deleted.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

If your label changes are handled through word processing, you should go ahead and address the following comments in addition to the above comments. Please submit a revised label for the Agency's review. However, if you are in the process of printing labels, you will need to submit a label amendment addressing these comments prior to your next label printing.

K. The use sites, commercial and industrial institutions, need to either be clarified or deleted.

L. Add specific use directions for disinfection in the following sites you claim: veterinary clinics, animal life science laboratories, pet shops, and kennels. The directions must also indicate specific surfaces for disinfection as well as the removal of the animals from the premises. The same set of directions may be used for all of the previously mentioned sites.

M. The first section under "General Use Directions" makes claims for disinfecting, cleaning and deodorizing. According to DIS/TSS-15 your product must have separate "Directions for Use" for disinfecting, cleaning and deodorizing. Include directions for cleaning and deodorizing.

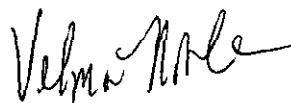
N. Provide specific directions for fungicidal activity.

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.

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

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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, nonporous 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:

SEP 21 1999

Under the Federal Insecticide,
Fungicide, and Rodenticide Act

Formulation HWS-128 (5/28/99) (EPA amendment) Page 1 of 2

registered under EPA Reg. 47371-130

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 *Adenovirus type 4
*Staphylococcus aureus*¹ *Avian polyomavirus
Salmonella choleraesuis *Canine distemper
Acinetobacter calcoaceticus *Feline leukemia
Bordetella bronchiseptica *Feline picornavirus
Chlamydia psittaci *Herpes simplex type 1
Enterobacter aerogenes *Herpes simplex type 2
Enterobacter cloacae *HIV-1 (AIDS virus)
*Escherichia coli*¹ *Infectious bovine rhinotracheitis
Fusobacterium necrophorum *Infectious bronchitis (Avian IBV)
*Klebsiella pneumoniae*¹ *Influenza A/Hong Kong
Legionella pneumophila *Pseudorabies
Listeria monocytogenes *Rabies
Pasteurella multocida *Rubella (German Measles)
Proteus mirabilis *Transmissible gastroenteritis virus (TGE)
Proteus vulgaris *Vaccinia
Salmonella enteritidis *Respiratory Syncytial virus (RSV)
Salmonella typhi
Salmonella typhimurium *Aspergillus niger*
Serratia marcescens *Candida albicans*
Shigella flexneri *Trichophyton mentagrophytes*
Shigella sonnei
Staphylococcus aureus -Methicillin Resistant (MRSA)
Staphylococcus aureus - Vancomycin Resistant (VRSA)
*Staphylococcus epidermidis*²
*Streptococcus faecalis*¹
Streptococcus pyogenes
Enterococcus faecalis - Vancomycin Resistant (VRE)
¹ ATCC & antibiotic-resistant strain
² antibiotic-resistant strain only

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride 4.85%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 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 (FIRST AID)

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 Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into 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.

(Reusable container statement:) Container can be reused once the container is empty. Empty container of concentrate into dilution dispenser [specific equipment such as "Simplex dispenser" can be named to replace "dilution dispenser"]. Dispenser will automatically dilute a sanitizer (or a disinfectant) solution. Remove concentrate label. Refill container with use dilution of concentrate from the dispenser. Replace cap with spray nozzle provided. Place correct use dilution label on the spray bottle.

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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.

CLEANING 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.

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, 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 21 1999

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

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