

MAY 29 1997

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

Subject: Formulation HWS-256
 EPA Registration No. 47371-129
 Notification Per PR-Notice 95-2

Attn: Ruth Trager
 Manager, Regulatory Services

This will acknowledge receipt of your notification regarding equivalent use-dilutions submitted under the provisions of FIFRA section 3 (c) 9. Based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

If you have any questions concerning this letter, please contact Zenobia Jones at (703) 309-6198.

Sincerely,

RSC

Rebecca S. Cool
 Product Manager 31
 Regulatory Management Branch 1
 Antimicrobial Division (7510W)

CONCURRENCES							
SYMBOL	7510W						
SURNAME	Z. Jones						
DATE	5-27-97						

(A) 	United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460 Application for Pesticide:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Registration</td> <td style="width: 50%;"><input type="checkbox"/> Amendment</td> </tr> <tr> <td><input checked="" type="checkbox"/> Other</td> <td></td> </tr> </table>	<input type="checkbox"/> Registration	<input type="checkbox"/> Amendment	<input checked="" type="checkbox"/> Other		OPP Identifier Number <div style="font-size: 24pt; font-weight: bold;">160801</div>
<input type="checkbox"/> Registration	<input type="checkbox"/> Amendment						
<input checked="" type="checkbox"/> Other							

Section I

1. Company/Product Number <div style="text-align: center;">47371-129</div>	2. EPA Product Manager <div style="text-align: center;">Marshall Swindell</div>	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) <div style="text-align: center;">FORMULATION HWS-256</div>	PM# <div style="text-align: center;">31</div>	
5. Name and Address of Applicant (Include ZIP Code) H & S CHEMICALS DIVISION LONZA INC. 17-17 ROUTE 208 FAIR LAWN, NJ 07410 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section II

<input type="checkbox"/> Amendment - Explain below <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - explain below.
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Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION - ADDITIONAL EQUIVALENT USE DILUTIONS OF:

- one (1) ounce of the concentrate per two (2) gallons of water
- two (2) ounces of the concentrate per four (4) gallons of water
- two and one half (2.5) ounces of the concentrate per five (5) gallons of water

Section III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Unit Package wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes," Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) of Retail Container	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label Is Affixed To Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other ()	

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name <div style="text-align: center;">RUTH TRAGER</div>	Title <div style="text-align: center;">Manager, Regulatory Services</div>	Telephone No. (Include Area Code) <div style="text-align: center;">201-794-2466</div>	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received <div style="text-align: center;">(Stamped)</div>
2. Signature 	3. Title <div style="text-align: center;">Manager, Regulatory Services</div>		
4. Typed Name <div style="text-align: center;">RUTH TRAGER</div>	5. Date <div style="text-align: center;">4/18/97</div>		

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FORMULATION HWS-256/
(Formulacion 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:

BACTERIA:

Pseudomonas aeruginosa¹
Staphylococcus aureus¹
Salmonella choleraesuis
Acinetobacter calcoaceticus
Bordetella bronchiseptica
Chlamydia psittaci
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli¹
Fusobacterium necrophorum
Klebsiella pneumoniae¹
Legionella pneumophila
Listeria monocytogenes
Pasteurella multocida
Proteus mirabilis
Proteus vulgaris
Salmonella enteritidis
Salmonella typhi
Salmonella typhimurium
Serratia marcescens¹
Shigella flexneri
Shigella sonnei
Staphylococcus aureus,
(methicillin resistant)
Staphylococcus epidermidis²
Streptococcus faecalis¹
Streptococcus pyogenes
Enterococcus faecalis
(Vancomycin Resistant)

*VIRUSES:

*Adenovirus type 4
*Avian polyomavirus
*Canine distemper
*Feline leukemia
*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
*Pseudorabies
*Rabies
*Respiratory syncytial virus (RSV)
*Rubella (German Measles)
*Transmissible gastroenteritis virus (TGE)
*Vaccinia

FUNGI:

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 NET CONTENTS (insert container size here)
EPA Est. No. 47371-IN-01

H&S CHEMICALS DIVISION
c/o LONZA Inc.
17-17 Route 208, Fair Lawn, NJ 07410

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PELIGRO: SI NO PUEDE LEER EN INGLÉS, 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

ONE (1) OUNCE PER TWO (2) GALLONS OF WATER
TWO (2) OUNCES PER FOUR (4) GALLONS OF WATER
TWO AND ONE HALF (2.5) OUNCES PER FIVE (5) GALLONS OF WATER

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(For products that list medical devices on the label, the following paragraph 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 preclean 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 1/2 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.

***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.

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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.

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.

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.

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.

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.

(For container sizes 5 gallons or larger, 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.

(For container sizes one gallon or less, use the following storage and disposal statements:)

STORAGE AND DISPOSAL

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

(For container sizes greater than one gallons, use the following storage and disposal statements:)

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 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.

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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 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.

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