

47371-131

07/24/2003

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 24 2003

Robert J. Sloan
Sr Regulatory Services Specialist
H & S Chemicals Division c/o Lonza Inc
17-17 Route 208
Fair Lawn, NJ 07410

Subject: Notification per PR Notice 98-10
Formulation HWS-64
EPA Reg. No. 47371-131
Application Dated: July 9, 2003
Receipt Date: July 10, 2003

Dear Mr. Robert J. Sloan,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification

- Modify use directions by replacing the phrase "per gallon of water" with the phrase "per gallon of *deionized water*" in the Citrus Canker Disease Control directions

General Comments

Based on a review of the material submitted, the following comments apply:

This application for notification is acceptable. A copy has been inserted in the file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6233.

Sincerely,

Velna Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobial Division (7510C)

CONCURRENCES

SYMBOL	7510(C)						
IRNAME	A Petos						
DATE	7/24/03						

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. EPA
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Velma Noble (PM-31)

Lonza Inc
17-17 Route 208
Fair Lawn, NJ 07410, USA

Robert J. Sloan
Performance Chemicals
Regulatory Services

Phone: (201) 794-2610
Fax: (201) 696-3569
bob.sloan@lonza.com

July 9, 2003

H&S Chemicals Division
Formulation HWS-64
EPA Reg. No. 47371-131

Notification of deletion/addition of non-public health pest per PR Notice 98-10, section II.B

Dear Ms. Noble,

Lonza is submitting a **Notification of deletion/addition of non-public health pest**. Lonza is deleting the current claim against Citrus Canker Disease (*Xanthomonas axonopodis pv. Citri*) and replacing it with a nearly identical claim against the same pest. The only difference in the claims is that the use directions are modified to specifically require the use of deionized water in the preparation of the use solution. In effect, the only requested change to the label is the replacement of the phrase "per gallon of water" with the phrase "per gallon of *deionized* water" in the Citrus Canker Disease Control directions.

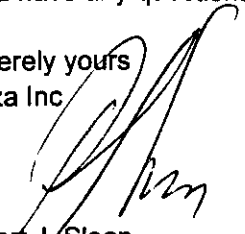
In support of this amendment, enclosed are the following:

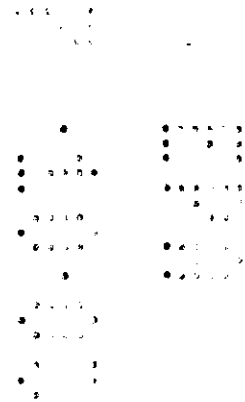
1. EPA Form 8570-1, Application for Pesticide Amendment, OPP ID No. 281152.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If you have any questions, please call me at 1-800-777-1875, ext. 2610.

Sincerely yours
Lonza Inc


Robert J. Sloan
Sr. Regulatory Services Associate



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080, Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number
281152

Application for Pesticide - Section I

1. Company/Product Number 47371-131	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Formulation HWS-64	PM# Team 31	
5. Name and Address of Applicant (Include ZIP Code) H&S Chemicals Division c/o 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"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification of deletion/addition of non-public health pest per PR Notice 98-10, section II.B

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
<i>Certification must be submitted</i>		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container - 30 ounces		5. Location of Label Directions <input type="checkbox"/>	
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 Robert J. Sloan	Title Sr. Regulatory Services Associate	Telephone No. (Include Area Code) (201) 794-2610
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 (Stamped)
2. Signature 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Robert J. Sloan	5. Date 7/9/03	

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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 mist. 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.

FORMULATION HWS-64

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	2.54%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₀ 10%) dimethyl benzyl ammonium chloride.....	1.69%
Inert Ingredients:.....	95.77%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-131
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

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(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 (VRE)
*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)
 *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

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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: (1:64) 2 ounces per gallon of water
(860 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 2 ounces of the concentrate per gallon of water. The use-solution can be applied with a cloth, mop, sponge, or coarse spray or by 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-64, 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 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) 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV 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). HBV is 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 2 oz. of Formulation HWS-64 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.

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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 2 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: 1:64 2 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 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 2 oz. of **FORMULATION HWS-64** 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 1:21 use-dilution (24¼ oz. per 4 gallons of deionized 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.

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(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.