

47371-164

09/05/2003



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SEP - 5 2003

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

Subject: Formulation HS - 1210(50%)
EPA Reg. No. 47371-164
Application Dated: Aug 06, 2003
Receipt Date: Aug 07, 2003

Dear Robert J. Sloan

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3 (c)9. is acceptable.

Proposed Amendment

- Replacement of the phrase "*and any other equipment*" with the phrase "*and any other hard nonporous equipment*"

Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to Replace a phrase is acceptable. A copy of this file has been placed in our records.

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

Sincerely,

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

CONCURRENCES					
YMBOL	7510c				
JRNAME	DALOMSKA				
ATE	8-27-03				

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

August 6, 2003

H&S Chemicals Division
Formulation HS-1210 (50%)
EPA Reg. No. 47371-164

Notification of clarification of use site for a non-public health pest per PR Notice 98-10

Dear Ms. Noble,

Lonza is submitting a **Notification of clarification of use site for a non-public health pest per PR Notice 98-10**. The requested change to the label is the replacement of the phrase "and any other equipment" with the phrase "and any other *hard nonporous* equipment" 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. 301908.
2. Two copies of the proposed label, with one copy highlighted for ease of review.

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



Read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

3/9



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
301908

Application for Pesticide - Section I

1. Company/Product Number 47371-164	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Formulation HS-1210 (50%)	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.)
Replacement of the phrase "and any other equipment" with the phrase "and any other hard nonporous equipment" in the Citrus Canker Disease Control directions

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	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	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		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
<p align="center">Certification</p> <p>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.</p>		6. Date Application Received (Stamped)
2. Signature 	3. Title Sr. Regulatory Services Associate	
4. Typed Name Robert J. Sloan	5. Date 8/6/03	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if swallowed or absorbed through the skin. May be fatal if inhaled. Do not breathe vapor or spray mist. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. 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 SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably 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. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not apply in marine and/or estuarine oil fields.

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

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.

PHYSICAL/CHEMICAL HAZARDS

This pesticide is a cationic germicide. Do not mix with soap or anionic materials. Do not use or store near heat or flame.

**FORMULATION HS-1210 DISINFECTANT /
SANITIZER (50%)**

ONE-STEP DISINFECTANT

SANITIZER - GERMICIDE - DEODORANT

Salmonellacidal Bactericidal Pseudomonacidal
Staphylocidal Fungicidal *Virucidal

Active Ingredients:

Didecyl dimethyl ammonium chloride..... 30.00%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
dimethyl benzyl ammonium chloride 20.00%
Inert Ingredients: 50.00%
Total..... 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-164

EPA Est. No. (as indicated on container)

Net Contents: (as indicated on container)

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

(Note to reviewer: The following is considered optional marketing language):

A concentrated, multi-purpose germicide and deodorant effective in a moderate amount of organic soil (5% serum) according to the AOAC Use-dilution Test.

Disinfects and deodorizes hard nonporous surfaces in one labor saving step.

Use in hospitals, nursing homes, medical clinics, dental offices, schools, colleges, office buildings, hotels and motels, airports, restaurants, bars, beverage plants, citrus plants, breweries, federally inspected meat and poultry plants, veterinary clinics and animal life science laboratories, tack shops, pet shops, breeding and grooming establishments, kennels, poultry and turkey farms, equine farms, dairy farms and hog farms.

Use on hard, nonporous surfaces such as floors, walls, lavatory fixtures, showers, machinery and equipment, garbage cans, metal, stainless steel, glazed porcelain, painted and plastic surfaces.

Bactericidal at 1:1000 dilution (2 oz. per 15½ gallons of water) against Pseudomonas aeruginosa, Staphylococcus aureus, and Salmonella choleraesuis according to the AOAC Use-Dilution Test method, modified in the presence of 5% organic serum. (See reference sheet for complete list of pathogenic organisms).

- DISINFECTANT (1:1000)2 oz. per 15½ gallons of water (500 ppm)
- SANITIZER (1:3333) 1 oz. per 26 gallons of water (150 ppm)
- SANITIZER (1:2496) 1 oz. per 19½ gallons of water (200 ppm)

DIRECTIONS FOR USE

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

DISINFECTION / DEODORIZING DIRECTIONS:

If surfaces are visibly dirty, preclean prior to disinfection / deodorizing activity. Prepare a solution of 2 oz. of product per 15½ gallons of water. Apply use-solution with a cloth, sponge, mop, coarse trigger sprayer, or by soaking to thoroughly wet all surfaces. Let solution remain on the surface for a minimum contact time of 10 minutes. Wipe dry with a clean cloth or sponge or allow to air dry. The use solution is prepared fresh for each use then discarded. Rinsing of floors is not necessary unless they are to be waxed or polished. Food contact surfaces must be thoroughly rinsed with potable water.

(Note to 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

or

This product is not to be used on medical device surfaces.

VIRUCIDAL DIRECTIONS*:

Virucidal against Bovine rhinotracheitis, Avian Infectious Bronchitis virus, and Newcastle Disease virus, Marek's Disease Virus and Infectious Bronchitis Virus - Arkansas strain (IBV) according to the virucidal qualification, modified in the presence of 5% organic serum at a 1:1000 dilution. Follow Disinfection Directions.

FUNGICIDAL DIRECTIONS:

Fungicidal against Trichophyton mentagrophytes (and Candida albicans and Aspergillus glaucus) according to the AOAC fungicidal test, modified in the presence of 5% organic serum at a 1:1000 dilution. For fungicidal activity use in areas such as locker rooms, dressing rooms, shower and bath areas, and exercise facilities. Follow Disinfection Directions.

MOLD AND MILDEW CONTROL DIRECTIONS: To control mold and mildew on hard, nonporous surfaces wash visible soil from the surface. Then apply a use-solution of 2 fluid oz. per 15½ gallons with a mop, sponge, cloth, or coarse trigger sprayer so as to wet all surfaces thoroughly. Let air dry. Repeat application every 7 days to control recurrence of growth.

FISHERY, MILK, CITRUS, ICE CREAM & POTATO PROCESSING PLANTS DISINFECTION DIRECTIONS:

Applied routinely as a disinfectant on walls and floors will reduce or eliminate odors in the processing area. Use on filling equipment to reduce or eliminate odors in the processing area and bacteria associated with condensation on equipment and pipes. Follow Disinfection Directions.

FOR SANITIZING FOOD CONTACT SURFACES:

Effective against the following according to the AOAC Germicidal & Detergent Sanitizer Test

- modified in the presence of 800 ppm water hardness (calculated as CaCO₃):
Escherichia coli
Staphylococcus aureus
- modified in the presence of 500 ppm water hardness (calculated as CaCO₃) against:
Campylobacter jejuni
Salmonella choleraesuis

For use on precleaned, hard, nonporous food contact surfaces including plastic and other hard nonporous cutting boards and chopping blocks, counter tops, tables, cooking and eating utensils and drinking glasses. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of sanitizing solution.

Use 1 oz. per 19½ - 26 gallons of water (200 - 150 ppm quat) for a minimum contact time of 1 minute in a single application.

Can be applied with a cloth, sponge, mop, coarse trigger sprayer, or by soaking. Eating utensils and drinking glasses must be sanitized by immersion. Thoroughly wet all surfaces. Drain thoroughly and air dry. Do not rinse.

Fresh sanitizing solution must be prepared at least daily or more often if the use solution becomes diluted. For mechanical applications, use solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Before use as a sanitizer in federally inspected meat and poultry plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

RESTAURANT AND BAR USE: For use as a sanitizer on dishes, glassware, silverware and eating and cooking utensils. For heavily soiled areas, remove gross food particles by preflush, prescrape and presoak when necessary. Wash thoroughly with detergent or compatible cleaner then rinse with potable water prior to application of this product. Then immerse in a solution of 1 oz. per 19½ - 26 gallons of water (200- 150 ppm quat) for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment, after cleaning thoroughly rinse equipment with cold or lukewarm water. Fill equipment with solution of 1 oz. per 19½ - 26 gallons of water (200 - 150 ppm quat). Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution should be drained from the system. To insure the removal of flavors, it is suggested that during changeover between products the system should be cleaned, rinsed and flushed with the sanitizing solution for at least 1 minute. Allow to drain completely before using. Do not rinse.

SANITARY FILLING: Recommended for use in sanitizing bottles or cans in the final rinse application. The product is to be proportioned into the final rinse water line of the container washer or rinser in concentration of 150-200 ppm active quat. A sanitizing solution of 150 - 200 ppm active quat should be used in an external application for the filler and closing machine. Do not rinse.

STORAGE TANK SANITIZING: Recommended for sanitizing beer fermentation and holding tanks. A solution of 150 - 200 ppm active quat should be applied manually or used in combination with automated cleaning systems. Follow directions for sanitizing food contact surfaces. Drain thoroughly. Do not rinse. For mechanical operations or automated systems, the used sanitizing solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR SANITIZING IN FISHERIES, MILK, CITRUS, POTATO & ICE CREAM PROCESSING PLANTS: For use as a sanitizer on conveyors and equipment to reduce or eliminate odors in the processing area. Also, for use on filling equipment to reduce bacteria associated with condensation on equipment and pipes. Follow directions for sanitizing food contact surfaces.

**FOR WISCONSIN ONLY
SANITIZING EATING AND DRINKING UTENSILS
IN EATING ESTABLISHMENTS**

- 1) Scrape and pre-wash utensils and glasses whenever possible.
- 2) Wash with a good detergent or compatible cleaner.
- 3) Rinse with potable water.
- 4) Sanitize in a solution of 1 fluid oz. per 19½ - 26 gallons of water. Immerse all utensils for at least two minutes or for a contact time specified by governing sanitary codes.
- 5) Place sanitized utensils on a rack or drain-board to air dry.
- 6) Prepare fresh sanitizing solution at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

POULTRY & TURKEY HOUSE DISINFECTANT DIRECTIONS:

Dilution: 1:1000 2 ounces per 15½ gallons of water

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks, and other feeding and water appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

FARM PREMISE DISINFECTANT DIRECTIONS:

For use in Equine, Dairy and Hog farms

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, 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, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

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 hard nonporous equipment taken into infested areas.

Saturate surfaces with a 1:250 use-dilution (5 oz. per 9¼ gallons 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. Clothing should be thoroughly rinsed or laundered before reuse. Footwear should be rinsed before reuse.

VETERINARY CLINICS / ANIMAL LIFE SCIENCE LABORATORY / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENT / TACK SHOP

DISINFECTION DIRECTIONS: For cleaning and disinfecting the following hard nonporous surfaces: equipment, utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles and crates. 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 product per 15½ gallons of water (or equivalent dilution) for a period of 10 minutes. 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers and other equipment that dispenses food or water with soap or detergent and rinse with potable water before reuse.

(REFERENCE SHEET FOR COMPLETE LIST OF PATHOGENIC ORGANISMS)

BACTERICIDAL AGAINST:

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

- Pseudomonas aeruginosa
- Staphylococcus aureus
- Salmonella choleraesuis

- Enterobacter aerogenes
- Escherichia coli
- Klebsiella pneumoniae
- Mycoplasma gallisepticum
- Proteus mirabilis
- Salmonella typhi
- Serratia marcescens
- Shigella flexneri
- Staphylococcus aureus phage 80
- Staphylococcus aureus phage 81
- Streptococcus pyogenes

VIRUCIDAL AGAINST*:

Effective against the following according to the virucidal qualifications modified in the presence of 5% organic serum.

- Avian Infectious Bronchitis virus
- Bovine rhinotracheitis virus
- Newcastle virus
- Marek's Disease Virus
- Infectious Bronchitis Virus, Arkansas strain (IBV)

FUNGICIDAL & MILDEWCIDAL AGAINST:

Effective against the following according to the AOAC Use-Dilution Test, modified in the presence of 5% organic serum.

- Aspergillus glaucus
- Candida albicans
- Trichophyton mentagrophytes

(If container size is one gallon or less, use the following Storage and Disposal statements):

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash or recycle.

(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

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 incineration or, if allowed by state and local authorities, by burning. 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 by other procedures approved by state and local authorities.

