

47371-37

12/2/2009

1 of 14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC -2 2009

Joanna Holcombe
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: Formulation HS-267Q
EPA Reg. No.: 47371-37
Notification Date: November 2, 2009
EPA Receipt Date: November 3, 2009

Dear Ms. Holcombe,

This letter acknowledges receipt of your notification submitted in connection with registration under the provisions of PR Notice 98-10 and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9.

Proposed Notification
Adding 2009 H1N1 Marketing Claims

General Comments

Based on a review of the submitted materials, your notification to add 2009 H1N1 Marketing Claims in accordance with the Agency guidance for testing labeling claims against Pandemic 2009 H1N1 Influenza A (Formerly called Swine Flu) is acceptable. A copy has been placed in our records for future reference.

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 II
Antimicrobial Division (7510P)

CONCURRENCES						
SYMBOL						
SURNAME						
DATE						

Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approval expires -98

EPA United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 47371-37	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FORMULATION HS-267Q	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) H&S Chemicals Division Lonza Inc. 90 Boroline Road Allendale, NJ 07401 <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 label change to add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1

Not Subject to PRIA

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 may be subject to enforcement action and penalties under Sections 12 and 14 of FIFRA.

Signature: Joanna Holcombe Date: 10/30/09

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No <i>*Certification must be submitted</i>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging 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)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) 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"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Joanna Holcombe	Title Sr. Commercial Regulatory Services Associate	Telephone No. (Include Area Code) 201-316-9297
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 <u>Joanna Holcombe</u>	3. Title Sr. Commercial Regulatory Services Associate	
4. Typed Name Joanna Holcombe	5. Date October 30, 2009	

Via FedEx

Ms. Velma Noble, PM-31
Document Processing Desk (NOTIFY)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Lonza Inc
Allendale
90 Boroline Road
Allendale, NJ 07401, USA

Joanna Holcombe
Lonza Life Science Ingredients
Commercial Regulatory Services

Tel 201-316-9297
Fax 201 696-3470
joanna.holcombe@lonza.com

October 30, 2009

SUBJECT: Formulation HS-267Q, EPA Registration No. 47371-037
Application for Label Notification

Dear Ms. Noble:

The purpose of this notification is to add the following:

Add optional marketing language per EPA Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1.

Please find enclosed the following documents in support of this label notification.

- Application for Pesticide Notification
• One copy of the label with changes highlighted

Please provide your decision electronically to me at joanna.holcombe@lonza.com and subsequently send me a letter confirming the Agency's decision. If you have any questions or need any additional information, please feel free to contact me at 201-316-9297.

Sincerely,
Lonza Inc.

Handwritten signature of Joanna Holcombe

Joanna Holcombe
Sr. Commercial Regulatory Services Associate

Vertical text on the right side of the page, possibly a barcode or tracking information.

40914

HS-267Q

One-Step Germicidal Cleaner and Deodorant

DISINFECTANT
STAPHYLOCIDAL
BACTERICIDAL
MILDEWSTATIC

PSEUDOMONACIDAL
SALMONELLACIDAL
FUNGICIDAL
*VIRUCIDAL

Active Ingredients:

Didecyl dimethyl ammonium chloride..... 1.875%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
dimethyl benzyl ammonium chloride.. 1.250%
Other Ingredients:..... 96.875%
Total..... 100.000%

KEEP OUT OF REACH OF CHILDREN

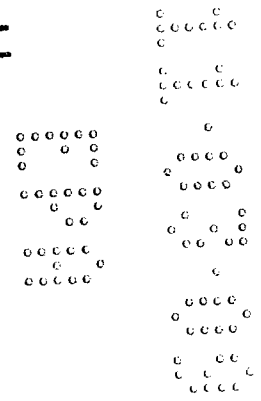
WARNING (AVISO)

EPA Reg. No. 47371-37
EPA Est. No. (as indicated on container)
Net Contents (as indicated on container)

(DOT symbols)
(Barcode)

H&S CHEMICALS DIVISION
c/o Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

NOTIFICATION
Date Reviewed: 12/2/09
Reviewed By: V. Noble



**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

WARNING. Causes substantial but temporary eye injury. Harmful if absorbed through skin. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Remove contaminated clothing and wash before reuse. Avoid contact with skin. Wash thoroughly with soap and water after handling.

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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

(If container size is 5 gallons or larger, use the following Environmental Hazards statement :)

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.

A multi-purpose, germicidal detergent effective in the presence of a moderate amount of organic soil (5% serum).

(Odor counteractant)

Disinfects, cleans, and deodorizes in one labor saving step.

Effective against the following pathogens:

(Bacteria:)

Pseudomonas aeruginosa (Pseudomonas)

Staphylococcus aureus (Staph)

Streptococcus pyogenes (Strep)

Enterobacter aerogenes

Enterobacter cloacae

Escherichia coli

Klebsiella pneumoniae

Mycoplasma gallisepticum

Proteus mirabilis

Proteus vulgaris

Salmonella enterica

Serratia marcescens

Shigella flexneri

Shigella sonnei

Staphylococcus aureus phage 80 & 81

Staphylococcus epidermidis

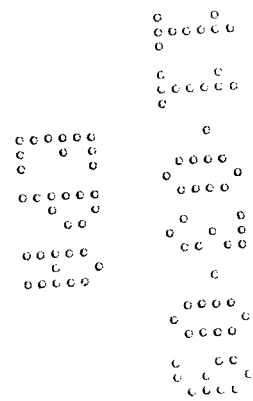
Staphylococcus aureus - Methicillin-Resistant [MRSA]

(Viruses:)

*Adenovirus Type 3

*Herpes simplex Type 1 (Herpes)

*HIV-1 (AIDS virus)



- *Influenza A/Texas (Influenza)
- *Rubella (German Measles)
- *Vaccinia (Pox Virus)

(Animal Viruses:)

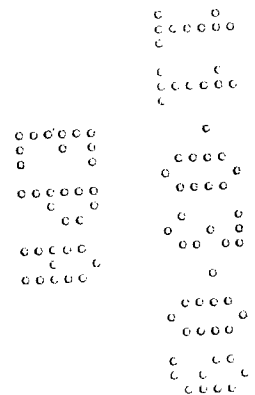
- *Avian influenza
- *Bovine rhinotracheitis virus
- *Infectious bronchitis (Avian IBV)
- *Newcastle disease virus

(Fungi:)

- Aspergillus flavus
- Aspergillus fumigatus
- Aspergillus glaucus var tonophilus
- Candida albicans
- Trichophyton mentagrophytes (Athlete's Foot Fungus)

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

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus. This product (Product Name) is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.
- This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).
- Kills Pandemic 2009 H1N1 influenza A virus.



Use **HS-267Q** in:

Bathrooms
Homes (households)
Kitchens

Dental offices
Hospitals
Medical Offices (Clinics)
Nursing homes

Day care centers
Nurseries

Bars
Cafeterias
Convenience stores
Federally inspected meat and poultry plants,
Food processing plants
Food storage areas
Institutional kitchens
Restaurants
(USDA) (Federally) inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons (Beauty)

Camp grounds
Play ground equipment
Animal laboratories
Dairy farms
Farms (Farm premises)
Hog farms
Kennels
Pet animal quarters
Pet shops
Poultry farms
Poultry houses
Turkey farms
Veterinary clinics
Zoos

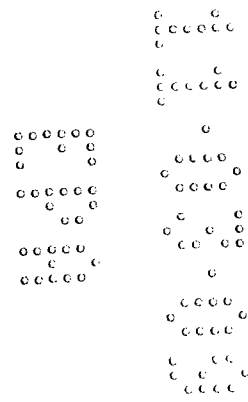
Airplanes
Airports
Boats
Buses

HS-267Q

EPA No. 47371-37

EPA Stamped label 9-26-07 with 5-19-09 Notification

(Note to reviewer: Language in () is optional or interchangeable)



- Campers
- Cars
- Emergency vehicles
- Mobile homes
- Ships
- Taxis
- Trailers
- Trains
- Transportation terminals

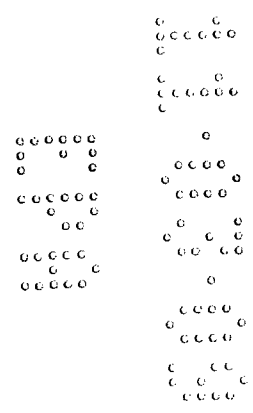
(TYPES OF SURFACES:)

Use HS-267Q on washable hard, nonporous surfaces of:

- Exterior surfaces of Appliances
- Basins (empty)
- Bathroom (lavatory) fixtures
- Bathtubs
- Cabinets
- Cages
- Chairs
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Conductive flooring
- Counters (countertops)
- Desks
- Doorknobs
- Floors
- Garbage cans
- Highchairs
- Kennel runs
- Exterior surfaces of Microwave ovens
- Outdoor furniture
- Exterior surfaces of Refrigerators
- Refrigerated storage and display equipment
- Showers
- Shower stalls
- Sinks (bathroom, kitchen)
- Stoves (stovetops)
- Tables, (picnic tables)
- Telephones
- Toilets
- Toilet bowls
- Toilet bowl surfaces
- Tubs
- Tiles, glazed
- Urinals
- Walls

Other hard nonporous surfaces made of:

- Formica®
- Glazed ceramic
- Glazed enameled surfaces
- Glazed porcelain
- Metal
- Painted surfaces
- Plastic (such as polystyrene or polypropylene)
- Sealed stone
- Stainless steel
- Upholstery, vinyl and plastic
- Woodwork, finished



DILUTION: 1:64 2 oz. per gallon of water (488 ppm Active Quat)

[If the following Spanish statement is used, it must appear directly above DIRECTIONS FOR USE.]

AVISO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

DIRECTIONS FOR USE

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

GENERAL USE DIRECTIONS

APPLICATION: For disinfection, remove heavy soil deposits from surface. Then thoroughly wet surface with a solution of 2 ounces of the concentrate per gallon of water. Apply with a cloth, mop, sponge, or coarse sprayer, or by soaking. For sprayer applications, use a coarse spray device. Spray 6-8-inches from surface, rub with a brush, cloth or sponge. Do not breathe spray. Let solution remain on surface for a minimum of 10 minutes. Rinse or wipe dry with a clean cloth or sponge or allow to air dry.

Rinse all surfaces that come in contact with food such as countertops, exterior surfaces of appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes.

Rinsing of floors is not necessary unless they are to be waxed or polished.

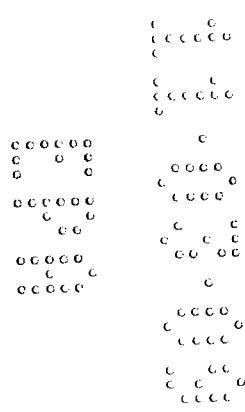
Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

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

(or)

This product is not for use on medical device surfaces.



USDA: 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.

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 materials must be removed from the room or carefully protected. All surfaces must be thoroughly rinsed with potable water.

TOILET BOWLS: To clean, apply diluted solution around the bowl and up under the rim. Stubborn stains may require brushing. To disinfect, first preclean to remove heavy soil, then remove or expel over the inner trap the residual bowl water. Pour in 3 ounces of the diluted solution. Swab the bowl completely using a scrub brush or mop, making sure to get under the rim. Let stand for 10 minutes or overnight, then flush.

DISINFECTION OF BARBER / BEAUTY / SALON INSTRUMENTS AND TOOLS: Tools (such as combs, brushes, razors, scissors, and other shop tools) can be disinfected by immersing in a 2 ounce per gallon solution for a contact time of 10 minutes. Prepare a fresh solution daily or more often if the solution becomes diluted or visibly soiled.

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 [2 ounces (1/4 cup) per gallon of water] with a cloth, mop, sponge, or coarse sprayer, making sure to wet all surfaces completely. Let air dry. Prepare a fresh solution for each use. Repeat application weekly or when growth reappears.

FOR FUNGICIDAL ACTIVITY: HS-267Q is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus) in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

***KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED, ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS** in healthcare 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 (HIV1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection: Clean-up should always be done wearing protective gloves, gowns, masks and eye protection.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of HS-267Q.

Contact Time: Leave surface wet for 5 minutes at 25°C (77°F) (room temperature). Use a 10-minute contact time for disinfection against all other viruses, fungi, and bacteria claimed.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

FARM PREMISE, LIVESTOCK, TURKEY AND POULTRY HOUSE DISINFECTANT:

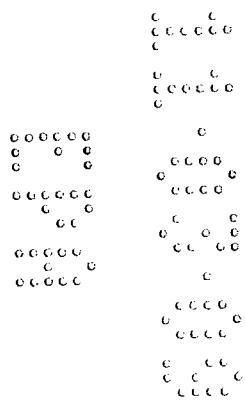
1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and 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, automated feeders, fountains, and waterers with soap and detergent, and rinse with potable water before reuse.

**VETERINARY PRACTICE / ANIMAL CARE / ANIMAL LABORATORY / ZOOS / PET SHOP / KENNELS
DISINFECTION DIRECTIONS:**

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries. 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. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 oz. of **HS-267Q** per gallon of water (*or equivalent dilution*) for a period of 10 minutes. Wipe or allow to air dry. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

HEAVY-DUTY CLEANING INSTRUCTIONS:

Use (1 oz of **HS-267Q** per 24 oz of water) (4 to 6 oz of **HS-267Q** per gallon of water) to clean heavily soiled areas.



(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has Household and Residential Uses only:)

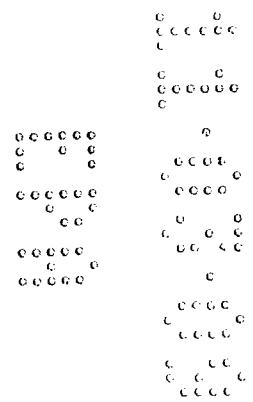
STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for reconditioning if appropriate.



(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has any uses other than Household and Residential)

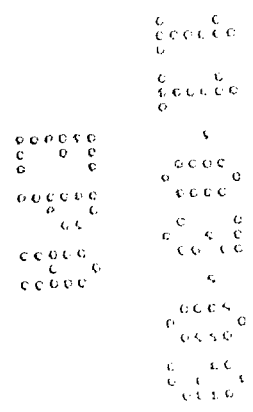
STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Do not store on side. Avoid creasing or impacting of side walls

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for recycling if available.

(or)

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap [container] and put in trash or offer for reconditioning if appropriate



(Note to reviewer: For Nonrefillable Containers, Container is over one gallon:)

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage:

Store in original container in areas inaccessible to children. Open dumping is prohibited.

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:

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying.

(Plastic Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. If not tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities.

(Metal Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. If not tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. DO NOT cut or weld metal containers.

