

47371-180

8/24/2010

10/15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 24 2010

Ms. Joanna Holcombe
Sr. Commercial Regulatory Services Associate
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: **Formulation HS-1210 Disinfectant/Sanitizer 14.08%**
Registration Number 47371-180
Application Dated May 26, 2010
EPA Received Date May 27, 2010

Dear Ms. Holcombe:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

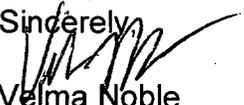
Proposed Amendment:

- Update Storage & Disposal Section PR Notice 2007-4

General Comments:

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,

Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	Enclosure: stamped label						
SURNAME							
DATE							

20/15

FORMULATION HS-1210 DISINFECTANT / SANITIZER (14.08%)

ONE-STEP DISINFECTANT

SANITIZER – GERMICIDE – DEODORANT

Salmonellacidal – Bactericidal – Pseudomonacidal – Staphylocidal – Fungicidal - *Virucidal

Active Ingredients:

Didecyl dimethyl ammonium chloride	8.448%
n-Alkyl (C ₁₄ 50%, C ₁₂ 40%, C ₁₆ 10%) dimethyl benzyl ammonium chloride	5.632%
Inert (Other) Ingredients:	85.920%
Total	100.000%

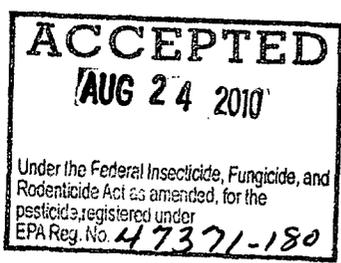
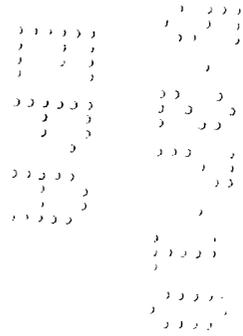
KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg. No. 47371-180
 EPA Est. No. (as indicated on container)
 Net Contents: (as indicated on container)
 [Country of origin (insert country)]
 [Manufactured in (insert country)]
 [Barcode]

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



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

A concentrated, multi-purpose germicide and deodorant effective in 5% organic 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.

- (Kills) (Eliminates) (Removes) (Destroys) 99.9% of bacteria
- (Kills) (Eliminates) (Removes) (Destroys) 99.9% of bacteria, leaves (leaving) surfaces (clean and) disinfected
- (Kills) (Eliminates) (Removes) (Destroys) [*Insert pathogen or pathogens other than avian influenza A from lists on pages 12-13*] (on (pre-cleaned) environmental surfaces)
- Kills germs

[Note to reviewer: Only when 550 ppm dilution is required]

- (Kills) (Eliminates) (Removes) (Destroys) avian influenza A (H5N1) on pre-cleaned environmental surfaces

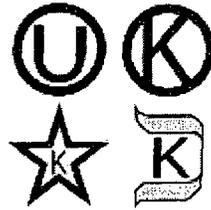
(Note to reviewer. The following may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.)



(NSF Listed)

(Insert NSF 6-Digit Listing Number here)

(Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.)



(Any Kosher Symbol such as:)

(Kosher)

Bactericidal against Pseudomonas aeruginosa, Staphylococcus aureus, and Salmonella enterica according to AOAC Use-Dilution Test method, modified in the presence of 5% organic serum. (See reference sheet for complete list of pathogenic organisms).

[Note to reviewer: For use only when sanitizer dilution is 150 ppm or higher]

Formulation HS-1210 Disinfectant / Sanitizer (14.08%) is effective at 150 ppm active quat according to the AOAC Germicidal & Detergent Sanitizer Test modified in the presence of 800 ppm water hardness (calculated as CaCO₃) against:

- Escherichia coli (E. coli)
- Staphylococcus aureus

[Note to reviewer: For use only when sanitizer dilution is 150 ppm or higher]

Formulation HS-1210 Disinfectant / Sanitizer (14.08%) is effective at 150 ppm active quat according to the AOAC Germicidal & Detergent Sanitizer Test modified in the presence of 500 ppm water hardness (calculated as CaCO₃) against:

- Escherichia coli (E. coli)
- Staphylococcus aureus

[Note to reviewer: For use only when sanitizer dilution is 200 ppm or higher]

Formulation HS-1210 Disinfectant / Sanitizer (14.08%) is effective at 200 ppm active quat according to the AOAC Germicidal & Detergent Sanitizer Test modified in the presence of 500 ppm water hardness (calculated as CaCO₃) against:

- Campylobacter jejuni
- Escherichia coli (E. coli)
- Escherichia coli 0157:H7(pathogenic E. coli)
- Listeria monocytogenes
- Salmonella enterica
- Shigella sonnei
- Staphylococcus aureus
- Vibrio Cholerae
- Yersinia enterocolitica

(PELIGRO: 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.

- DISINFECTANT 1:256 1/2 oz. per gallon of water
.....(550 ppm)
- SANITIZER 1:938..... 2 oz. per 14 1/2 gallons of water
.....(150 ppm)
- SANITIZER 1:704..... 2 oz. per 11 gallons of water
.....(200 ppm)
- SANITIZER 1:352..... 2 oz. per 5 1/2 gallons of water
.....(400 ppm)

DISINFECTION / DEODORIZING DIRECTIONS:

If surfaces are visibly dirty, preclean prior to disinfection / deodorizing activity.

Prepare a solution of 1/2 ounce of product per gallon of water. Apply use-solution with a cloth, sponge, mop, coarse trigger sprayer, or by soaking to thoroughly wet all surfaces. For sprayer applications, use a coarse spray device. Spray 6 – 8 inches from the surface, rub with a brush, cloth or sponge. Do not breathe spray. 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 is not necessary unless floors 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. [optional: 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, *Avian Influenza (Virus) (H5N1), 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 1:256 dilution. Follow Disinfection Directions.

FUNGICIDAL DIRECTIONS:

Fungicidal against Trichophyton mentagrophytes and Candida albicans according to the AOAC fungicidal test, modified in the presence of 5% organic serum at a 1:256 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 ½ fluid oz. per gallon of water 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 odor causing bacteria associated with condensation on equipment and pipes. Follow Disinfection Directions.

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FOR SANITIZING FOOD CONTACT SURFACES:

or

For Food Contact Surfaces, Food Processing Equipment and Utensils in Dairies and Public Eating Establishments and Food Contact Surfaces, Food Processing Equipment and Utensils in Food Processing Plants (40 CFR 180.940 (a)):

[Note to reviewer: Only one dilution from this table may be used in the paragraphs below]

- 2 oz. per 14 1/2 gallons of water (150 ppm quat) (or equivalent dilution)
- 2 oz. per 11 - 14 1/2 gallons of water (150 – 200 ppm quat) (or equivalent dilution)
- 2 oz. per 11 gallons of water (200 ppm quat) (or equivalent dilution)
- 2 oz. per 5 1/2 gallons of water (400 ppm quat) (or equivalent dilution)
- 2 oz. per 5 1/2 - 14 1/2 gallons of water (150 – 400 ppm quat) (or equivalent dilution)
- 2 oz. per 5 1/2 – 11 gallons of water (200 – 400 ppm quat) (or equivalent dilution)

For use on precleaned, hard, nonporous food contact surfaces including plastic and other hard nonporous cutting boards and chopping blocks, counter tops, tables, food preparation surfaces, 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 *[insert dilution from table here]* for a minimum contact time of 1 minute in a single application. *(Alternate language for closed loop dilution center:)* Then use product from the Closed Loop Dilution Center (*[insert concentration from table here]*) for a minimum contact time of 1 minute in a single application.

Apply 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, 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 *[insert dilution from table here]* for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

(Alternate language for closed loop dilution system:)

RESTAURANT AND BAR USE:

For use as a sanitizer on dishes, glassware, silverware, 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 sanitizing solution from Closed Loop Dilution Center (*[insert concentration from table here]*) for at least 1 minute. Drain thoroughly and air dry. Do not rinse.

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 2 fluid ounces per 11 – 14½ gallons of water (150 – 200 ppm quat). 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 a 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, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940).

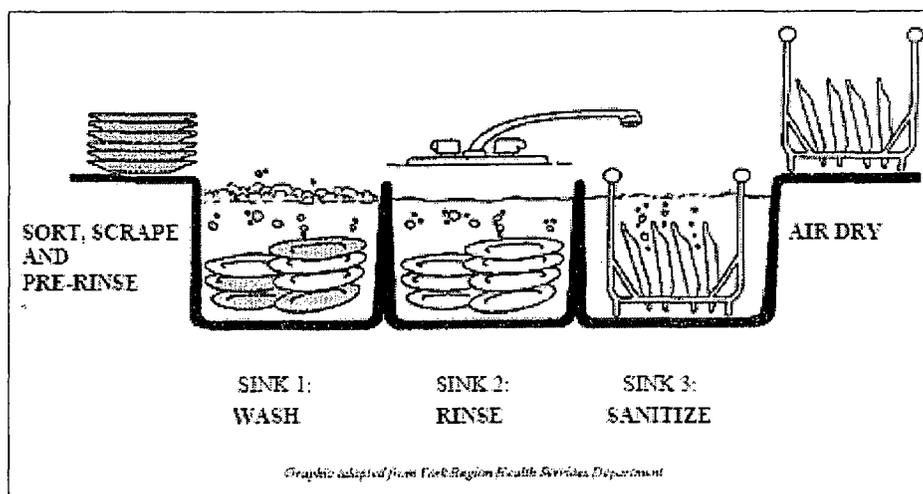
(Alternate language for closed loop dilution center:)

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 from the Closed Loop Dilution Center (2 fluid ounces per 11 - 14 1/2 gallons of water (150 – 200 ppm quat)). 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) Fresh sanitizing solution must be prepared at least daily or when visibly soiled or diluted.

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940).

(Note to reviewer: The following graphic or a graphic of similar content may accompany any of the above food contact sanitization sections)



BEVERAGE PLANTS: For sanitizing of bottling or pre-mix dispensing equipment. After cleaning, thoroughly rinse equipment with cold or lukewarm water. Fill equipment with a solution of *[insert dilution from table here]*. Allow the solution to remain in contact with equipment for at least 1 minute or until operations resume at which time the sanitizing solution must 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: 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 *([insert concentration from table here])* ppm active quat. Use a sanitizing solution of *([insert concentration from table here])* ppm active quat in an external application for the filler and closing machine. Do not rinse.

STORAGE TANK SANITIZING: For sanitizing beer fermentation and holding tanks. A solution of *([insert concentration from table here])* active quat is to 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 odor causing bacteria associated with condensation on equipment and pipes. Follow directions for sanitizing food contact surfaces.

110915

["SPECIAL INSTRUCTIONS FOR INACTIVATING AVIAN INFLUENZA A" AND OTHER ANIMAL VIRUSES LISTED ON THIS LABEL]

[VETERINARY], [ANIMAL CARE] and [ANIMAL LABORATORY] FACILITIES/ [ZOOS] / [PET SHOPS] / [KENNELS] / [BREEDING AND GROOMING ESTABLISHMENT] / [TACK SHOP] [AND] [FARM PREMISE] DISINFECTION / [VIRUCIDAL] DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries pens, stalls and etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and 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 1/2 oz. 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. Thoroughly scrub all treated surfaces, then rinse all surfaces that come in contact with food, including equipment used for feeding or watering, with potable water before reuse. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

POULTRY & TURKEY HOUSE DISINFECTANT DIRECTIONS:

Dilution: 1:256 ½ ounce per gallon 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 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 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.

**VETERINARY CLINICS / ANIMAL CARE / ANIMAL LIFE SCIENCE LABORATORY / PET SHOP / ZOO
/ 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, etc. Remove all animals and feeds from premises, animal transportation vehicles, 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 ½ oz. of product per gallon 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.

CITRUS CANCKER 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. Apply treatments 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 1:70 use-dilution (2¾ oz. per 1½ 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. Thoroughly rinse or launder clothing before reuse. Rinse footwear 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 enterica

Aeromonas salmonicida
Campylobacter jejuni
Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Listeria monocytogenes
Mycoplasma gallisepticum
Proteus mirabilis
Pseudomonas putida
Salmonella typhi
Serratia marcescens
Shigella flexneri
Staphylococcus aureus phage 80
Staphylococcus aureus phage 81
Streptococcus pyogenes
Vibrio anguillarum

FUNGICIDAL & MILDEWCIDAL AGAINST:

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

Alternaria tenuis
Aspergillus glaucus
Candida albicans
Fusarium oxysporum
Geotrichum candidum
Penicillium digitatum
Phytophthora infestans
Rhizopus nigricans (stolonifer)
Trichoderma harzianum
Trichophyton mentagrophytes

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(REFERENCE SHEET FOR COMPLETE LIST OF PATHOGENIC ORGANISMS)

VIRUCIDAL AGAINST*:

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

Avian Infectious Bronchitis virus

Avian Influenza (Virus) (H5N1)

Bovine rhinotracheitis virus

Newcastle virus

Marek's Disease Virus

Infectious Bronchitis Virus, Arkansas strain (IBV)

(Note to reviewer: For Nonrefillable Containers for commercial, industrial, and institutional uses – all sizes – No Reuse Rinsate Statement for Public Health Use products. Chapter 13, Table 6 of the Label Review Manual states that for "All products in containers that could be burned," the registrant has the option to "Remain silent on burning;" therefore, no incineration language is provided for plastic containers.)

STORAGE AND DISPOSAL

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

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

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 and Metal Containers:) Triple rinse as follows: Fill container $\frac{1}{4}$ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(For metal containers only: DO NOT cut or weld metal containers.)

(For Bag in Box Containers:) Completely empty bag into application equipment. Then offer for recycling if available or dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.