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2-12-2001 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 1 2 2001

Franklin Cleaning Technology P.O. Box 214 Great Bend, KS 67530

Subject: AQ+ EPA Registration No. 1124-102 Amendment Dated October 2, 2000

Attn: Elaine Wagle Sr. Regulatory Affairs Coordinator

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment.

The Findings for the Confidential Statement of Formula (CSF) are as follows: The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredient given in the Basic Formulation CSF agreed with the percentages declared on the label. Upper and lower certified limits for the active ingredient, Bardac 205M were not acceptable. The certified limits must be based on the nominal concentration of 7.5% which represent the total actives present in Bardac - 205M.

Item 2 of the CSF, producer name and address, was not provided as required. The source of the active ingredients utilized in AQ+ was misstated.

This sanitizer is approved for food-contact surfaces as per 21 CFR 178.1010. Product Chemistry Data for Guidelines Series 61, 62 and 63 was complete and consistent with the chemistry of quaternary ammonium compounds. All other elements of the CSF were acceptable.

This applicant for amended registration, updating the CSF and label for AQ+ to meet the requirements of PR Notice 91-2, is accepted with comment. Corrections requested under "Findings" should be made at the earliest convenient time.

CONCURRENCES											
SYMBOL	17510C										
SURNAME	13. Jones										
DATE	12-8-01										
EPA Form 1320-1A (1/90)			Printed on Recycled Paper				OFFICIAL FILE COPY				

☆GPO : 2000 - 187-381

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

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Sincerely,

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

### PRECAUTIONARY STATEATENTS HAZARDS TO HUMANS AND DOMESTIC ANIETALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), clothing and rubber gloves when handling. Harmful if swallowed and/or if absorbed through the skin. Do not breath spray mist.

# FIRST AID

If in eyes, hold eyelids open and flush with a steady gentle stream of water for 15 minutes. Get medical attention. If on skin, wash with plenty of soap and water. Get medical attention. If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

### (For one gallon package size or less) STORAGE AND DISPOSAL

Keep product under locked storage, inaccessible to small children. Do not reuse empty container. Rinse thoroughly, securely wrap empty container in several layers of newspaper and discard in trash.





ACCEPTED with COMMENTS

in EPA Letter Dated:

FEB 1 2 2001

Under the Federal Insecticide, Fangicide, and Rodenticide Act as amended, for the pesticido, registered under EPA Reg. No. 1124-102

amended, tor the pesicide, DISINFECTANT • SANITIZER • FUNGICIDE • DEODORIZER • VIRUCIDAL egistered under EPA Reg. No. 1124-102

> KEEP OUT OF REACH OF CHILDREN. DANGER - PELIGRO become the set of the set o

Sanitizer for food and non-food contact surfaces. Hospital disinfectant. Effective in the presence of 5% serum contamination.

	ACTIVE INGREDIENTS:			
100 A	Aikyi (C <sub>14</sub> 50%, C <sub>12</sub> 40%, C benzyi emmonium chloride Octvi decvi dimethyi emmo	nium chioride	 EPA <b>Reg</b> . No. 112 EPA Est. No. 625	24-102 11-KS-1
	Diociyi dimethyi ammonlur	n chloride		
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**NET CONTENTS** 

# DIRECTIONS FOR USE

AQ+ may be used in hospitals, homes, medical and dental offices, nursing homes, day care centers, nurseries, restaurants, restaurants and bars, cafeterias, institutional kitchens, convenience stores, food storage areas, institutional facilities, public rest rooms, institutions, schools, athletic facilities, camp grounds, play grounds, public facilities, food processing plants, dairy farms, hog farms, poultry and turkey farms, egg processing plants, kennels, pet animal quarters, zoos, pet shops, animal laboratories, laundries, transportation terminals, hotels and motels, factories, business and office buildings, boats, ships, campers, trailers, mobile homes, cars, buses, trains, taxis, airplanes, humidifier water tanks.

AQ+ may be used on washable hard non-porous surfaces including food preparation and storage areas, dishes, glassware, silverware, cooking utensils, coolers, ice chests, refriderator meat and vedetable and egg bins, Tupperware®, kitchen equipment such as food processors, blenders, cutlery and other utensils, countertops, slurpy machines, stovetops, sinks, appliances, refrigerators, tables, picnic tables, outdoor furniture, chairs, desks, telephones, highchairs, washable walls, cabinets, doorknobs, baby toys, telephones, shower stalls, tubs and tiles, toilets, portable toilets, porcelain tiling, garbage cans, exhaust fans, refrigerated storage and display equipment, coils and drain pans of air conditioning and refrigeration equipment and heat pumps, beer fermentation and holding tanks, bottling or pre-mix dispensing equipment, stainless steel, enameled surfaces, woodwork, Formica®, vinyl, leather and plastic upholstery, bathtubs, shower stalls, sinks, urinals, toilet bowls, toilet bowl surfaces, related fixtures, walls, kennel runs, capes, floors, conductive flooring and other hard non-porous surfaces (such as metal, stainless steel, glazed porcelain, ceramic, fiberglass, stone and glastic). Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion. No potable water rinse is required.

When used as directed, AQ+ will deodorize surfaces in restroom and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors. AQ+ deodorizes moist hard non-porous surfaces by killing microorganisms that cause offensive odors.

AQ+ is recommended for Poultry Premise Sanitation (Hatcheries): Egg Receiving Area, Egg Holding Area, Setter Room, Tray Dumping Area, Trays, Buggies, Racks, Egg Flats, Chick Holding Room, Hatchery Room, Chick Processing Area, Chick Loading Area, Poultry Buildings, Ceilings, Sidewalls and Floors, Drinkers, and all other Poultry House related Equipment, and all other surfaces in the Hatchery Environment.

DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

AQ+ is recommended for use in federally inspected meat and poultry plants as a sanitizer for all surfaces not always requiring a rinse. Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

#### Sanitizer Directions for Non-Food Contact Surfaces:

Preparation of Sanitizer Use-Solution: Add 0.25 oz. of AQ+ per gallon of water (150 ppm active, 1:512 ratio) to sanitize hard, nonporous surfaces. At 150 ppm active, AQ+ is an effective one-step sanitizer, against Staphylococcus aureus and Klebsiella pneumoniae. Apply sanitizer use-solution to precleaned, hard nonporous surfaces with a cloth, mop, sponge, spraver or by immersion.

For sprayer applications, use a coarse mist pump or trigger sprayer. Spray 6-8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray mist, NOTE: With spray applications, cover or remove all food products.

Treated surfaces must remain wet for 1 minute, then wipe with sponge, mop or cloth or allow to air dry.

#### Sandizer Directions for Fond Contact Surfaces

For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard surfaces.

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrabe and, when necessary, presoak. Then thoroughly wash or flush objects with a good detergent or compatible cleaner, followed by a potable water rinse before application of the sanitizing solution.

Product# F273022

Apply a solution of 1 oz. - 1.36 oz. of AQ+ per 4 gallons of water (153-200 ccm active-1:512 to 1:375ratio) to precleaned hard surfaces thoroughly wetting surfaces with a cloth mop, sponge, sprayer or by immersion. Surfaces should remain wet for at least one minute -(60 seconds) followed by adequate draining and air drying. Fresh solution should be prepared daily or when use solution becomes visibly dirty. For mechanical application, use solution may not be reused for sanitizing applications. No potable water rinse is required after application of the sanitizing solution.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by cloth or brush. No potable water rinse is required. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in a solution of 0.25 - 0.34 oz. of AQ+ per gallon of water (1 oz. - 1.36 oz. A0+ per 4 gallons of water: 150-200 ppm active, 1:512 to 1:375 ratio). No potable water rinse is required.

At 0.25 oz. per gallon (150 ppm active, 1:512 ratio), AQ+ is an effective food contact sanitizer, in water up to 400 ppm hardness against Escherichia coli and Staphylococcus aureus. At 0.34 oz. per gallon (200 ppm active, 1:375 ratio), AQ+ is an effective food contact sanitizer, in water up to 500 ppm hardness against Escherichia coli, Escherichia coli

0157:H7, Listeria monocytogenes and Staphylococcus aureus. AQ+ is an effective funcicide against Trichophyton mentagrophytes (the athlete's foot fungus) when used on surfaces in areas such as locker rooms, dressing rooms, shower and ended, for the pesticide, bath areas, exercise facilities.

with COMMENTS in EPA Letter Dated: FEB 1 2 2001

ACCEPTED

Under the Federal Insecticide. Fungicide, and Rodenticide Act as registered under EPA Reg. No. 1124-102

Salon /Barber Instruments and Tools Sanifizer Directions:

Immerse precleaned salon / barber instruments and tools (such as combs, brushes, razors and scissors, blades and manicure instruments) in a use-solution of 0.34 oz, per gallon of water (or equivalent dilution)(200 ppm active, 1:375 ratio) for at least 60 seconds. Binse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes 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.

**U.S. PUBLIC SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS** 

CLEANING AND SANITIZING. Equipment and utensils shall be thoroughly preflushed or prescraped and when necessary, presoaked to remove gross food particles and soil. 1. Thoroughly wash equipment and utensils in a hot detergent solution. 2. Rinse utensils and equipment thoroughly with clean water. 3. Sanitize equipment and utensils by immersion in a solution of 0.25 - 0.34 oz. AQ+ per gallon of water (1 oz. - 1.36 oz. per 4 gallons of water; 150 - 200 ppm active, 1:512 to 1:375 ratio) for at least 60 seconds at a temperature of 75°F. This dilution is equivalent to a solution containing 50 ppm available chlorine, 4. For equipment and utensils too large to sanitize by immersion, apply a solution of 1 oz. AQ+ per 2 gallons of water (300 ppm active, 1:256 ratio) by rinsing, spraying or swabbing until thoroughly wetted. 5. Allow sanitized surface to drain and air dry. Do not rinse.

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

1. Scrape and pre-wash utensils and plasses whenever possible. 2. Wash with a good detergent or compatible cleaner. 3. Rinse with clean water. 4. Sanitize in a solution of 0.34 oz, per 1 gallon of water (200 ppm active, 1:375 ratio). Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code. 5. Place sanitized utensils on a rack or drain board to air dry.

#### Beverage Discussing Equipment Southzer Directions:

Fill equipment with a use-solution of 0.25 - 0.34 oz. of AQ+ per gallon of water (150-200 ppm active, 1:512 to 1:375 ratio). Allow solution to remain in equipment for at least 60 seconds. Drain thoroughly and allow to air dry berry reuse. A rinse is not required.

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### Sanitary Filling Equipment Sanitizer Directions

Prepare a use-solution of 0.25 - 0.34 oz. of AQ+ per gallon of water (150-200 ppm active, 1:512 to 1:375 ratio) for final washer and rinse applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse. A rinse is not required.

#### Storage Tanks Sanitizer Directions:

Recommended for sanitizing beer fermentation and holding tanks. Prepare a use-solution of 0.25 oz.- 0.34 oz AQ+ per gallon of water (150-200 ppm active, 1:512 to 1:375 ratio) for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse. A rinse is not required,

#### Humidifiers Sanitizer Directions:

Thoroughly clean water tank and fifters. For initial fill, add 0.34 oz, of AO+ per gallon of water (200 pm active, 1:375 ratio). For refill water, add 0.34 oz. AQ+ per gallon of water (200 ppm active, 1:375 ratio). Not for use in heat or atomizing type humidifiers.

#### To Sanifize Egg Shells Intended for Food:

To sanitize previously cleaned food-grade eggs in shell egg and egg product processing plants, spray with a use-solution of 0.25 - 0.34 oz. of AD+ per gallon of warm water (150 - 200 ppm active, 1:512 to 1:375 ratio). The solution should be warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs should be reasonable dry before casing or breaking. The solution should not be re-used for sanitizing eggs. Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.

AQ+ is a Hospital Disinfectant at 0.78 oz. per gallon dilution (450 ppm active, 1:164 ratio). Bactericidal according to the current AOAC Disinfectants Use-Dilution Method, Fungicidal according to the AOAC fungicidal test, and Virucidal\* according to the virucidal qualification. modified in the presence of 5% organic serum against:

Brevibacterium ammoniagenes, Campylobacter jejuni, Escherichia coli, Escherichia coli pathogenic strain 0157:H7, Klebsiella pneumoniae, Listeria monocytogenes, Pseudomonas aeruginosa, Pseudomonas cepacia, Salmonella choleraesuis, Salmonella typhi, Staphylococcus aureus, Yersinia enterocolitica, Trichophyton mentagrophyles, \*Influenza A2 / Hong Kong, "Herpes Simplex Type I, "Herpes Simplex Type II," Vaccinia.

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces minimizes the probability of contaminating food during preparation, storage or service which could harbor hazardous microorganisms. Effective cleaning will remove soil and prevent the accumulation of food residues that may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those disease organisms which may be present on equipment and utensils after cleaning, and reduces the potential for the transfer, either directly through tableware such as glasses, cups and flatware or indirectly through food.

To orevent cross-contamination, kitchenware and food-contact surfaces of equipment shall be washed, rinsed and sanitized after each use and following any interruption of operation during which time contamination may have occurred.

Where equipment and utensils are used for the preparation of foods on a continuous or production-line basis, utensils and the food-contact surfaces of equipment shall be washed. rinsed and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

Veterinary Practice / Animal Care / Animal Laboratory Disorfection Directions Recommended for cleaning and disinfecting hard nonporous surfaces including equipment. utensils, instruments, cages, kennels, stables, catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, and enclosures. Remove all litter, droppings and manure from floors, walls and surfaces of facilities and fixtures occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 0.78 oz of AQ+ per gallon of water (450 ppm active, 1:164 ratio) (or equivalent dilution) for a period of 10 minutes. Ventilate buildingand other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

#### Faim Premise Use:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, cutes and other facilities and fixtures occupied or traversed by animals. Empty all throughs, racks and other tending and watering appliances. Thoroughly clean all surfaces with soap or detergent and ruse with water. Saturate all surfaces with a use-solution of 0.78 oz of AQ+ per galign of water (450 pom active, 1,164 ratio) (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, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, manders: troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

#### Disinfectant, Marcide (Emgivide Orections

Preparation of use-solution:

Add 0.78 oz, of AQ+ per gallon of water (450 ppm active, 1:164 ratio). Apply use-solution to hard, nonporous surfaces with a cloth, mop, sponge, sprayer or by immersion, thoroughly, wetting surfaces. For sprayer applications, use a coarse mist pump or trigger sprayer. Spraynder the Federal Insecticide, 6 - 8 inches from surface, rub with brush, sponge or cloth. Do not breathe spray. NOTE: Pangicide, and Rodenticide Act as With spray applications, cover or remove all food products. Treated surfaces must remain amended, for the pesticide.

wet for 10 minutes. Wipe dry with a sponge, mop or cloth or allow to air dry. Prepare a registered under EPA Reg. No. fresh solution daily or when use solution becomes diluted or soiled. Food contact surfaces 1124-10-2 such as countertops, tables, picnic tables appliances and/or stovetops should be rinsed with potable water prior to reuse.

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.

#### Directines as a how Acid Tudet Boyd Disjet start

#### Remove gross fifth prior to disinfection.

From concentrate: Add 0.78 oz. of AQ+ to the toilet bowl or urinal and mix. Brush thoroughly over exposed surfaces and under the rim with a cloth, mop, or sponge, Repeat and allow to stand for 10 minutes and flush.

From use-solution: Empty toilet bowl or urinal and apply a use-solution of 0.78 oz, of AQ+ per gallon of water (450 ppm active, 1:164 ratio) (or equivalent dilution) to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Allow to stand for 10 minutes and flush.

### Directions as a located ant ( Fungicide - 'Viricide for Barber of Salon Instruments and Tools,

Completely immerse precleaned barber or salon instruments and tools (such as combs. brushes, razors and scissors, blades and manicure instruments) in a use-solution of 0.78 oz. of AQ+ per gallon of water (450 ppm active, 1:164 ratio) (or equivalent dilution) for at least 10 minutes. Rinse thoroughly and dry before use. For heavily soiled instruments, a preliminary cleaning is required. Fresh solution should be prepared daily or more often if solution becomes 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.

#### Deodorizer Directions:

Apply solution of 0.78 oz. of A0+ per callon of water (450 ppm active, 1:164 ratio) (or equivalent dilution) to surfaces to be deodorized.

ACCEPTED **V** with COMMENTS in EPA Letter Dated:



# (For over one gallon package size) 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 instructions contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** 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.

# **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.



ACCEPTED with COMMENTS in EPA Letter Dated: FEB 1 2 2001

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1124-102

