



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 3, 2017

Jonathon Walsh
Regulatory Assurance Specialist
Lonza Inc.
90 Boroline Road
Allendale, NJ 07401

Subject: PRIA Label Amendment – Modify efficacy related claims
Product Name: Bardac 205M-14.08
EPA Registration Number: 6836-278
Application Date: December 21, 2016
Decision Number: 524617

Dear Mr. Walsh:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and/or enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Norovirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

BARDAC™ 205M-14.08

Disinfectant - Sanitizer – Fungicide – Virucide* – Deodorizer

Effective in the presence of 5% serum contamination when used as a disinfectant

For Home, Hospital, Institutional and Industrial Use

For Farm, School, Dairy, Restaurant, Food Handling and Processing Areas, Bar and Institutional Kitchen Use

- Formulated for Effective Farm Premise Sanitation
- Formulated for Effective Poultry Premise Sanitation
- Formulated for Effective Swine Premise Sanitation
- Formulated for Effective Mushroom Farm Sanitation
- Formulated for Veterinary Practice / Animal Care / Animal Laboratory Disinfection

For use in federally inspected meat and poultry plants

An effective sanitizer for use on food contact surfaces

• Staphylocidal • Pseudomonacidal • Bactericidal • Fungicidal • Virucidal*

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	4.224%
Dioctyl dimethyl ammonium chloride	1.690%
Didecyl dimethyl ammonium chloride	2.534%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.632%
Other [Inert] Ingredients	85.920%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

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

EPA Reg. No. 6836-278

EPA Est. No. (*insert EPA Est. No. here*)

Net Contents: (*as indicated on container*)

[DOT symbols]

[Country of origin (*insert country*)]

[Manufactured in (*insert country*)]

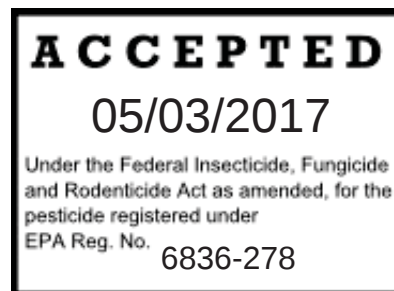
[Barcode]

Manufactured by:

Lonza Inc.

90 Boroline Road

Allendale, NJ 07401



PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Harmful if swallowed, inhaled or absorbed through the skin. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective (rubber, chemical resistant) gloves when handling. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. [For dilutions 400 ppm or less, protective eyewear, protective clothing and gloves are not required.]

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 by mouth-to-mouth, if possible.

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

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

{If container size is 5 gallons or greater, use the following Environmental Hazards statements:}

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

{Note to reviewer: the following is considered optional marketing language:}

- Concentrate [Concentrated]
- Deodorizes [Deodorizer]
- Disinfects [Disinfectant]
- [This product] Contains no [phosphates] phosphorous [or phosphorous compounds].

Bardac 205M-14.08:

- will deodorize surfaces in rest room and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and other places where bacterial growth can cause malodors.
- delivers non-acid disinfectant performance in an economical concentrate.
- is an economical concentrate
- can be diluted for use with a mop and bucket, trigger sprayers, sponge or by soaking.
- improves labor results by effectively controlling odors.
- is formulated for use in daily maintenance programs to deliver effective disinfecting and malodor control.
- will not leave grit or soap scum.
- is a versatile disinfectant for Veterinary Practice, Animal Care, Animal Laboratory and Farm Premise applications.
- deodorizes by killing microorganisms that cause offensive odors.
- is a complete, chemically balanced disinfectant and sanitizer that provides clear use solutions even in the presence of hard water.
- meets AOAC Use-Dilution Test Standards for hospital disinfectants.
- meets Sanitizer Test standards for non-food contact surface sanitizers. At 200 ppm active, **Bardac 205M-14.08** is an effective sanitizer by eliminating 99.9% of *Staphylococcus aureus* [*Enterobacter aerogenes*] and *Klebsiella pneumoniae* in 3 minutes.
- meets AOAC Germicidal & Detergent standards for sanitizing previously cleaned food-contact surfaces.
- has been cleared under 40 CFR 180.940 (a) for use on food Processing Equipment and Utensils [in Dairies and Public Eating Establishments] [and] [Food Contact Surfaces, Food Processing Equipment and Utensils] [in Food Processing Plants] [and] [other food-contact articles] [at a concentration of 150 ppm active] [at a concentration of 200 ppm active] [at a concentration of 400 ppm active] [at a concentration of 150 – 200 ppm active] [at a concentration of 150 – 400 ppm active] [at a concentration of 200 – 400 ppm active].
- is a disinfectant, sanitizer, fungicide, virucide, deodorizer for use in all federally inspected meat and poultry plants, hospitals, institutional and industrial facilities.
- can be used on food contact surfaces in a concentration [range] of [0.75 oz. per 5 1/2 gallons of water [150 ppm active]] [1.0 oz. per 5 1/2 gallons of water [200 ppm active]] [2.0 oz. per 5 1/2 gallons of water [400 ppm active]] [0.75 – 1.0 oz. per 5 1/2 gallons of water [150 – 200 ppm active]] [0.75 – 2.0 oz. per 5 1/2 gallons of water [150 – 400 ppm active]] [1.0 – 2.0 oz. per 5 1/2 gallons of water [200 – 400 ppm active]].
- For use in (*insert name of automated dilution system here*) [automated] [dilution system].
- makes (XXX) gallons at (YYY) use dilution
- is a No Rinse sanitizer formula.
- [Kills] [Eliminates] [Removes] [Destroys] avian influenza A (Turkey/Wisconsin) (H9N2) on pre-cleaned environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] (*Insert pathogen or pathogens from lists on pages 10 – 11*) on [pre-cleaned] environmental surfaces
- [Kills] [Eliminates] [Removes] [Destroys] [Germs] [Bacteria] [Viruses*] [on pre-cleaned environmental surfaces]
- [Kills] [Eliminates] [Removes] [Destroys] 99.99% of Foodservice Germs [*Escherichia coli* [E. coli], *Salmonella enterica* [Salmonella], and *Listeria monocytogenes* [Listeria]]
- [Kills] [Eliminates] [Removes] [Destroys] 99.99% of Foodservice Bacteria**
** [*Escherichia coli* [E. coli], *Salmonella enterica* [Salmonella], and *Listeria monocytogenes* [Listeria]]
- For Commercial Use

{Note to reviewer: The following is considered optional marketing language:}

Use **Bardac 205M-14.08**:

- as a disinfectant on hard, nonporous surfaces.
- for sanitizing and disinfecting of ultrasound transducers, probes, mammography compressor plates and other hard nonporous surfaces. Will not cause swelling of transducer membrane or harm compressor plates.
- on coils and drain pans of air conditioning and refrigeration equipment and heat pumps. Follow the directions for sanitization of non-food contact surfaces.
- as a broad spectrum disinfectant in Ultrasonic Baths [Ultrasonic cleaning units].
- to sanitize and disinfect [manicure] [nail] [salon] [barber] tools and instruments: combs, brushes, scissors, blades and manicure instruments.
- to clean and disinfect finished floors without dulling gloss.
- for [non-scratch] cleaning of showers and tubs, shower doors and curtains, fixtures and toilet bowls.
- in kitchens, bathrooms and other household areas.
- to disinfect sinks and tubs.
- 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 other hard nonporous surfaces in the Hatchery Environment.
- for Swine Premise Sanitation: Waterers and Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns and Areas, Nursery, Blocks, Creep Area, Chutes.
- for Farm Premise Sanitation: floors, walls, feed racks, mangers, troughs, automatic feeders, fountains and waterers, forks, shovels, scrapers and other nonporous surfaces in barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
- as a sanitizer on dishes, glassware, and utensils.
- as a sanitizer in bottling and beverage dispensing equipment.
- as a sanitizer in sanitary filling of bottles and cans.
- in sanitizing bottles or cans in the final rinse application, and for external spraying of filler and closing machines.
- as a sanitizer in beer fermentation and holding tanks.
- as a Food-Grade Shell-Egg sanitizer, with best results achieved in water temperatures ranging from 78°F. – 110°F. **Bardac 205M-14.08** may be applied through automatic washing systems, immersion tanks, foaming apparatus, and low pressure sprayers.
- in federally inspected meat and poultry facilities [as a sanitizer for all surfaces not always requiring a rinse].
- as a sanitizer for all surfaces not always requiring a rinse in official establishments operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.

Use [on] [to clean and disinfect] nonporous athletic mats, wrestling mats, gymnastic mats, exercise equipment and training tables.

Use [on] [to clean and disinfect] nonporous personal protective safety equipment, wrestling headgear, boxing headgear, protective headgear, athletic helmets, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, hearing protectors, and ear muffs. Rinse all equipment that comes in prolonged contact with skin with warm water and allow to air dry before reuse. [Precaution: Cleaning at 120°F. temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement.]

Cross-contamination is of major [housekeeping] [food safety] concern. **Bardac 205M-14.08** has been formulated to aid in the reduction of cross-contamination on treated surfaces not only in hospitals, but in schools, institutions, and industry.

{Not for Use in California:} Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. **Bardac 205M-14.08** provides residual bacteriostatic and self-sanitizing properties against odor-causing bacteria for laundered items such as diapers, hospital and institutional linen and athletic equipment.

{Note to reviewer: The following is considered optional marketing language:}

Bardac 205M-14.08 is a concentrated one-step [Hospital] disinfectant that is effective against a broad spectrum of bacteria, is virucidal*, fungicidal and eliminates odor-causing bacteria when used as directed.

Bardac 205M-14.08 is a phosphate free, germicidal detergent effective in the presence of a moderate amount of organic soil on hard nonporous surfaces found at mushroom farms. **Bardac 205M-14.08** has been designed for use between mushroom crops. Areas of intended use include breezeways and track alleys before spawning, inside and outside walls of mushroom houses, lofts, floors, storage sheds and casing rings. Use of **Bardac 205M-14.08** must be limited to areas where compost and mushrooms are not present.

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor food poisoning microorganisms minimizes the probability of contaminating food during preparation, storage or service. Effective cleaning will remove soil and prevent the accumulation of food residues, which may decompose or support the rapid development of food poisoning organisms or toxins. Application of effective sanitizing procedures reduces the number of those 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 prevent cross-contamination on treated surfaces, kitchenware and food-contact surfaces of equipment must be washed, rinsed with potable water 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 must be washed, rinsed with potable water and sanitized at intervals throughout the day on a schedule based on food temperature, type of food, and amount of food particle accumulation.

Articles that can be immersed in solution must remain in solution for 60 seconds. Articles or surfaces too large for immersing must be thoroughly wetted or flooded by rinsing, spraying or swabbing. Allow all sanitized surfaces to drain and air dry.

Bardac 205M-14.08 fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 2007 Recommendations of the U.S. Public Health Services in waters up to 500 ppm of hardness calculated as CaCO_3 when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

{Note to reviewer: the following is considered optional marketing language:}

[AREAS OF USE:]

Use **Bardac 205M-14.08** in:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}

Bathrooms
Homes [Households]
Kitchens

Clinics
Dental offices
Health Care Facilities
Hospitals
Medical Offices
Medical Related facilities
Nursing homes
Sick Rooms
Day care centers
Nurseries

Bars
Beverage Plants
Cafeterias
Convenience stores
Egg Processing Plants
Food Preparation Areas
Food processing plants
Food storage areas
Institutional kitchens
Restaurants [Front of House]
USDA inspected food processing facilities

Athletic facilities
Barber shops
Business and office buildings
Colleges
Correctional facilities
Dressing rooms
Exercise facilities
Factories
Hotels
Institutional facilities
Institutions
Laundries

Locker rooms
Motels
Prisons
Public facilities
Public rest rooms
Schools
Shower and bath areas
Salons [Beauty] [Tanning] [Nail] [Manicure]
Camp grounds
Play ground equipment
Universities

Animal laboratories [or] [clinics]
Dairy farms
Farms
Hog farms
Kennels
Mushroom Farms
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos

Airplanes
Airports
Ambulances
Boats
Buses
Campers
Cars
Emergency [Police] [EMS] [Fire] [Rescue] vehicles
Mobile homes
Ships
Taxis
Trailers
Trains [Train Cars] [Box cars] [Rail Cars]
Transportation terminals
Trucks [Box Trucks]

{Note to reviewer: the following is considered optional marketing language:}

[TYPES OF SURFACES:]

Use **Bardac 205M-14.08** on washable hard, nonporous surfaces of:

{Note to reviewer: Each entry below also represents a graphic depicting the corresponding type of surface. No people, animal, or food will be depicted in graphics. Only exteriors of microwaves and refrigerators will be depicted. Toy graphics will be submitted to Agency for review.}

Appliances, exteriors
Bathroom fixtures
Bathtubs [fiberglass]
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
Conductive flooring
Counters [Countertops]
Countertop laminates
Desks
Doorknobs [and Handles]
Floors
Foot Spas
Garbage cans
Highchairs
Kennel runs
Microwave ovens, exteriors [exterior surfaces of]
Outdoor [patio] furniture except cushions and wood frames
Refrigerators, exteriors [exterior surfaces of]
Refrigerated storage and display equipment
Showers
[Fiberglass] Shower stalls
[Fiberglass] Sinks [bathroom] [kitchen]
Sinks [bathroom] [kitchen]
Stoves [stovetops]
Tables, [Non-wooden picnic tables]
Tanning Beds
Telephones
Toilets

Toilet bowls
Toilet bowl surfaces
Tubs [Fiberglass]
Tiles, glazed
Ultrasonic baths
Urinals
Walls
Whirlpool [bathtubs] [tubs] [units]

Beer fermentation and holding tanks
Beverage dispensing equipment
Blenders
Bottling or premix dispensing equipment
Chopping blocks, plastic and other nonporous
Cooking utensils
Coolers
Cutlery
Cutting Boards, plastic and other nonporous
Dishes
Eating Utensils
Food processors
Food dispensing equipment
Frozen Drink [Beverage] Machines
Glassware
Ice Chests
Ice Machines
Ice cream dispensing equipment [Soft Serve]
Plastic Food Storage Containers
Kitchen equipment
Refrigerator bins used for meat, fruit, vegetables and eggs
Silverware

{Note to reviewer: the following is considered optional marketing language:}

[TYPES OF SURFACES:]

Use **Bardac 205M-14.08** on washable hard, nonporous surfaces of:

Non-critical [hospital] [medical] [Device] equipment surfaces:

Beds [Medical] [Hospital]

Bed frames

Bed rails

Crutches

Defibrillators

Gurneys

[Medical] Examining tables

[Medical] [Hospital] Lamps

Rescue tools

Resuscitators

[Medical] [Hospital] Scales

Stands

Stretchers

Stethoscopes

Walkers

Wheel chairs

Other hard nonporous surfaces made of:

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

Laminated surfaces

Metal

Plastic [such as polystyrene or polypropylene]

Sealed Granite

Sealed limestone

Sealed marble

Sealed Slate

Sealed Stone

Sealed Terra cotta

Sealed Terrazzo

Stainless steel

Upholstery, vinyl and plastic

Woodwork, finished

{Note to reviewer: one or more of the following must be used when making sanitizing claims depending on the use dilution selected}

Bardac 205M-14.08 is an effective sanitizer at 150 ppm active quat for use on food contact surfaces in 400 ppm hard water against:
Escherichia coli
Staphylococcus aureus

Bardac 205M-14.08 is an effective sanitizer at 200 ppm active quat for use on food contact surfaces in 500 ppm hard water against:
Campylobacter jejuni
Escherichia coli
Escherichia coli O157:H7
Klebsiella pneumoniae
Listeria monocytogenes
Salmonella enterica
Shigella sonnei
Staphylococcus aureus
Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS384] [USA300]
Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]
Staphylococcus aureus – Methicillin-Resistant [MRSA]
Yersinia enterocolitica
Vibrio cholerae

Bardac 205M-14.08 is an effective sanitizer at 400 ppm active quat for use on food contact surfaces in 1000 ppm hard water against:
Escherichia coli
Staphylococcus aureus

{Note to reviewer: The following is considered optional marketing language:}

Bardac 205M-14.08 is a [Hospital] Disinfectant, 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:

{or}

As a disinfectant, **Bardac 205M-14.08** [kills] [is effective against]:

[Bacteria:]

Burkholderia cepacia

Campylobacter jejuni [Campylobacter]

Corynebacterium ammoniagenes Escherichia coli [E. coli]

Escherichia coli pathogenic strain O157:H7 [pathogenic E. coli]

Klebsiella pneumoniae [Klebsiella]

Listeria monocytogenes [Listeria]

Pseudomonas aeruginosa [Pseudomonas]

Salmonella enterica [Salmonella]

Salmonella typhi [Salmonella]

Shigella dysenteriae [Shigella]

Staphylococcus aureus [Staph]

Staphylococcus aureus - Community Associated Methicillin-Resistant [CA-MRSA] [NRS123] [USA400]

Staphylococcus aureus - Methicillin-Resistant [MRSA]

Yersinia enterocolitica

[Viruses:]

*Adenovirus Type 5

*Adenovirus Type 7

*Hepatitis B Virus [HBV]

*Hepatitis C Virus [HCV]

*Herpes Simplex Virus Type 1 [Herpes]

*Herpes Simplex Virus Type 2 [Herpes]

*Human Coronavirus

*Human Immunodeficiency Virus Type 1 [HIV-1] [AIDS Virus]

*Influenza A2 / Hong Kong [Influenza] [Flu] Virus

*Norovirus - Feline Calicivirus

*SARS Associated Human Coronavirus

*Vaccinia Virus [Pox Virus]

- 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.

{Note to reviewer: The following is considered optional marketing language:}

Bardac 205M-14.08 [kills] [is effective against] [the following animal viruses]:

Arkansas '99 [Infectious Bronchitis Virus]
Avian Infectious Laryngotracheitis Virus
Avian Influenza Virus (Turkey/Wisconsin)
Avian Influenza Virus (H5N1)
Canine Distemper Virus
Feline Calicivirus
Marek's Disease Virus
Newcastle's Disease Virus
Pseudorabies Virus

[Fungi:]

Aspergillus niger

Trichophyton mentagrophytes [Athlete's Foot Fungus] [Cause of Ringworm] [A Cause of Ringworm of the foot]

Bardac 205M-14.08 is effective against Citrus Canker Disease [Xanthomonas axonopodis pv. citri].

{Note to Reviewer: These statements for claims against large non-enveloped, and/or enveloped emerging viral pathogens shall not appear on marketed (final print) product labels.}

Emerging Viral Pathogens – This product qualifies for claims against emerging large, non-enveloped or enveloped viral pathogens.

Bardac 205M-14.08 has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, **Bardac 205M-14.08** can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

OR

[Name of illness/outbreak] is caused by [name of emerging virus]. **Bardac 205M-14.08** kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

Dilution:

Disinfection [1:256]	1/2 oz. per gallon of water
.....	[550 ppm active quat]
Sanitizer [1:352]	2 oz per 5 1/2 gallons of water
.....	[0.37 oz. per gallon of water]
.....	[400 ppm active quat]
Sanitizer [1:704]	1 oz. per 5 1/2 gallons of water
.....	[3/4 oz per 4 gallons of water]
.....	[0.19 oz. per gallon of water]
.....	[200 ppm active quat]
Sanitizer [1:938]	3/4 oz. per 5 1/2 gallons of water
.....	[0.14 oz. per gallon of water]
.....	[150 ppm active quat]

DIRECTIONS FOR USE

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

DISINFECTION [VIRUCIDAL*] [FUNGICIDAL] [MOLD AND MILDEW CONTROL] DIRECTIONS:

Add 1/2 oz. of **Bardac 205M-14.08** per gallon of water [or equivalent dilution] to disinfect hard, nonporous surfaces.

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.

When used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities, this product is an effective fungicide against *Trichophyton mentagrophytes* [the athlete's foot fungus]. Follow disinfection directions.

Apply use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Do not breathe spray.

Note: For spray applications, cover or remove all food products.

Treated surfaces must remain wet for 10 minutes. *{Note to reviewer: if using reduced contact time for Human Coronavirus, the following sentence will be required:}* **[For Human Coronavirus** treated surfaces must remain wet for 1 minute.] Wipe dry with a clean cloth, sponge or mop or allow to air dry.

Rinse food contact surfaces such as counter tops, tables, picnic tables, appliances and / or stove tops with potable water prior to reuse. Do not use on glasses, dishes or utensils as a disinfectant.

For heavily soiled areas, a preliminary cleaning is required.

{or}

For heavily soiled areas, preclean first.

For mold and mildew, 1/2 oz. of **Bardac 205M-14.08** per gallon of water [or equivalent dilution] will effectively inhibit the growth of mold and mildew and the odors caused by them when applied to hard, nonporous surfaces. Follow disinfection instructions. Repeat treatment every seven days, or more often if new growth appears.

{Note to reviewer: one of the following two statements will be used:}

BACTERICIDAL STABILITY OF USE-DILUTION: Tests confirm that the use solution of this product, when stored in a sealed container such as a spray bottle, remains effective [up to 7 days] [for up to one week] [for up to one month] [for up to 2 months] [for up to 3 months] [for up to 4 months] [for up to 5 months]. If product becomes visibly dirty or contaminated, the use-dilution must be discarded and fresh product prepared. Always use clean, properly labeled containers when diluting this product. Bactericidal stability of the use-dilution does not apply to open containers such as buckets or pails.

{or, Above header Not needed}

Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or 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 pre-clean 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.

***KILLS HIV AND HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS**

in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS] or Hepatitis B Virus [HBV] or *Hepatitis C Virus [HCV].

Special Instructions for Cleaning and Decontamination against HIV-1 or HBV or HCV on Surfaces / Objects Soiled With Blood / Body Fluids.

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

Cleaning Procedure: Blood and other body fluids containing HIV-1 or HBV or HCV must be thoroughly cleaned from surfaces and objects before application of **Bardac 205M-14.08**.

Contact Time: Leave surfaces wet for 10 minutes with a 1/2 oz. per gallon of water use solution [or equivalent dilution].

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

NON-ACID TOILET BOWL AND URINAL DISINFECTANT DIRECTIONS:

Remove gross filth prior to disinfection.

From concentrate: Add 1/2 oz. of Bardac 205M-14.08 to the toilet bowl or urinal and mix. Brush thoroughly over exposed surfaces and under the rim with a cloth, mop or sponge. Allow to stand for 10 minutes and flush.

From use-solution: Empty toilet bowl or urinal and apply a use-solution of 1/2 oz. per gallon of water [or equivalent dilution] to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Brush or swab thoroughly, then allow to stand for 10 minutes and flush.

[NAIL] [MANICURE] [SALON] [BARBER] INSTRUMENTS AND TOOLS DISINFECTION [BACTERICIDE] [VIRUCIDE*] [FUNGICIDE] DIRECTIONS:

Mix 1/2 oz. of **Bardac 205M-14.08** per gallon of water [or equivalent dilution] to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, plastic rollers, razors, scissors, blades, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if the solution becomes visibly diluted, cloudy or soiled.

Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean, non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

ULTRASONIC BATH DISINFECTANT DIRECTIONS:

Use **Bardac 205M-14.08** to disinfect hard nonporous non-critical instruments / objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 1/2 oz. of **Bardac 205M-14.08** per gallon of water [or equivalent dilution] directly into bath chamber. Preclean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturer's use directions. Remove objects and rinse with sterile water [sterile water for injection], or allow to air dry. Prepare a fresh solution for each use.

WHIRLPOOL [BATH[S]] [UNIT[S]] DISINFECTION DIRECTIONS:

After using [whirlpool [bath] [unit]] drain and fill with a use solution of 1/2 oz. of **Bardac 205M-14.08** per gallon of water to [just cover the intake valve] [cover the highest jet] [2 inches above the highest jet]. Start the pump to circulate the solution. Wash down the [deck], unit sides, seat of the chair lift, and any related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the [bath] [unit] has been thoroughly disinfected, drain the solution from the unit and rinse disinfected surfaces with fresh water. Wipe dry with a clean sponge or cloth and allow to air dry.
Repeat for heavily soiled units.

WHIRLPOOL FOOT SPA DISINFECTION:

After using whirlpool foot spa, drain the water and thoroughly clean all hard nonporous surfaces with soap or detergent. Rinse with water. Saturate surfaces with ½ oz. of product per gallon of water to cover intake valve or 2 inches above highest jet. Start pump to circulate the solution. Swab exposed surfaces including unit sides, chair, and any related equipment thoroughly with cloth, sponge, or brush and allow treated surfaces and solution to stand for 10 minutes. After unit has been thoroughly disinfected, rinse all disinfected surfaces with fresh water.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use **Bardac 205M-14.08** at 1/2 oz. per gallon of water. Apply with a damp mop or autoscrubber.

Bardac 205M-14.08 [kills] [is effective against] [the following animal viruses]:
{include list from page 11}

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

{or}

[VETERINARY], [ANIMAL CARE] and [ANIMAL LABORATORY] FACILITIES/ [ZOOS] / [PET SHOPS] / [KENNELS] 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 [troughs, racks and] 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. of **Bardac 205M 14.08** 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. [For "Veterinary Practice..." Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse 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.

{Alternate Numbered Format}

For cleaning and disinfecting hard nonporous surfaces: equipment used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries pens, stalls and etc.

1. Remove all animals and feeds from premises, animal transportation vehicles, crates, pens, stalls and etc.
2. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.
3. Empty all [troughs, racks and] feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with a use-solution of 1/2 oz. of **Bardac 205M 14.08** per gallon of water [or equivalent dilution] for a period of 10 minutes. Wipe or allow to air dry.
6. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure.
7. 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. [For "Veterinary Practice..." Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse.]
8. 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 AND SWINE PREMISE DISINFECTION [/ VIRUCIDAL*] DIRECTIONS:

Remove all animals and feeds from premises, vehicles, and enclosures such as coops and crates. Remove all litter, droppings and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Use 1/2 oz. of **Bardac 205M 14.08** per gallon of water [or equivalent dilution] Saturate surfaces with the disinfecting solution for 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, trucks, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

Hatcheries:

Use to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard surfaces. Use 1/2 oz. of **Bardac 205M-14.08** per gallon of water. Leave all treated surfaces wet for 10 minutes or more. Allow to air dry.

Vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with **Bardac 205M-14.08** and water. Apply use solution to treat all vehicles. Use 1/2 oz. of **Bardac 205M-14.08** per gallon of water. Leave treated surfaces wet for 10 minutes or more. Allow to air dry.

Dressing Plant:

Disinfect equipment, utensils, walls and floors in poultry and animal dressing plants. Disinfect offal rooms, exterior walls and loading platforms of dressing plants. Cover or remove all food and packaging materials. Remove all heavy soils prior to application. Use 1/2 oz. of **Bardac 205M-14.08** per gallon of water. Saturate all and scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

MUSHROOM FARM PREMISE USE:

Site Preparation: The first step in any on-going sanitation program must be the removal of gross contamination and debris. This may be accomplished by using a shovel, broom, or vacuum, depending on the area to be disinfected.

Cleaning and Disinfection: For general cleaning and disinfection, use 1/2 oz. of **Bardac 205M-14.08** per gallon of water [or equivalent dilution]. Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first. Prepare a fresh solution for each use or more often if solution becomes visibly diluted, clouded or soiled.

For Heavy Duty Cleaning: When greater cleaning is desired, use 1 oz. of **Bardac 205M-14.08** per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

DO NOT APPLY THE USE-SOLUTION TO THE MUSHROOM CROP, COMPOST OR CASING. Rinse treated surfaces with potable water before they contact the crop, compost or casing.

CITRUS CANCER DISEASE CONTROL:

For prevention of Citrus Canker Disease through treatment of precleaned 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 harvesting equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other hard nonporous part of the equipment that can be taken into infested areas. Thoroughly clean all surfaces with soap or detergent and rinse with water. Then saturate surfaces with a 1:70 use-dilution [2 3/4 oz. of **Bardac 205M-14.08** per 1 1/2 gallons of distilled 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 must be either rinsed or laundered before reuse. Footwear must be rinsed before reuse.

TO SANITIZE NON-FOOD CONTACT SURFACES:

Add 1 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [or equivalent dilution] [200 ppm active] to sanitize precleaned hard, nonporous surfaces. Apply sanitizer use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Do not breathe spray.

Note: For sprayer applications, cover or remove all food products.

Treated surfaces must remain wet for 3 minutes. Wipe dry with a sponge, mop or cloth or allow to air dry. Prepare fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

TO SANITIZE [BARBER] [MANICURE] [NAIL] [SALON] INSTRUMENTS AND TOOLS: {Not for Use in California}

Immerse precleaned barber / salon instruments and tools [such as combs, brushes, razors, scissors, blades and manicure instruments] in a use-solution of 1 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [or equivalent dilution] for at least 3 [three] minutes. Rinse thoroughly and dry before use. Prepare a fresh solution daily or more often if solution becomes visibly diluted, cloudy or soiled.

NOTE: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.

LAUNDRY BACTERIOSTAT: {Not for Use in California}

Use 1.6 ounces per 75 pounds of dry weight fabric. Dilute the appropriate amount of **Bardac 205M-14.08** in one to two gallons of water then add to the washwheel in the final rinse. Re-treat fabric after each washing. For residual bacteriostatic activity against odor causing bacteria, conditions of high relative humidity or wet contamination are required. Laundered fabric may also be treated by soaking.

ALGAE AND SLIME CONTROL IN COOLING AND PROCESS WATERS: {Use not approved in the State of California}

Bardac 205M-14.08 is formulated to provide control of growth of algae and slime in recirculating cooling water systems and evaporative condensers as well as cooling tunnels and warmers. It can be used in cooling water for thermal processing and pasteurizing operations in dairies, breweries, soft drink and food canning plants. To control algae and bacterial slimes, use as directed. For best results, slug feed. Add directly from the product container using proper and accurate dispensing equipment. The frequency of addition needed depends on many factors. To optimize your use, follow this procedure:

Recirculating Cooling Towers, Dairy Sweetwater, and Other Process Waters: Initially use not more than 18 fluid ounces per 1,000 gallons of water to be treated (up to 20 ppm active quaternary). Increase dosage to 32 fluid ounces per 1,000 gallons of water, if necessary, except in dairy recirculating cooling water (commonly referred to as sweetwater) systems where dose is limited to not more than 20 ppm actives. Repeat initial dose every seven days or increase the frequency, if needed.

{Note to reviewer. On a final printed label, only one of the following dilution rates [or equivalent dilution] will be used in the sanitization sections below}

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)]:

3/4 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [0.14 oz. of **Bardac 205M-14.08** per gallon of water] [150 ppm active quat]

{or}

1 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [0.19 oz. of **Bardac 205M-14.08** per gallon of water] [200 ppm active quat]

{or}

2 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [0.37 oz. of **Bardac 205M-14.08** per gallon of water] [400 ppm active quat]

{or}

3/4 oz. of **Bardac 205M-14.08** per 5 1/2 - 4 gallons of water [0.14 – 0.19 oz. of **Bardac 205M-14.08** per gallon of water] [150 - 200 ppm active quat]

{or}

3/4 – 2 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [0.14 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [150 - 400 ppm active quat]

{or}

3/4 oz. of **Bardac 205M-14.08** per 2.07 – 5.5 gallons of water [0.14 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [150 - 400 ppm active quat]

{or}

1 – 2 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [0.19 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [200 - 400 ppm active quat]

{or}

1 oz. of **Bardac 205M-14.08** per 2 3/4 – 5 1/2 gallons of water [0.19 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [200 - 400 ppm active quat]

TO SANITIZE FOOD CONTACT SURFACES:

{or}

TO SANITIZE FOOD CONTACT SURFACES, FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS [IN A THREE COMPARTMENT SINK]:

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

Prior to application, remove gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak. 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.

Articles too large for immersing, apply a use-solution of *(insert appropriate dilution from box above here)* to the precleaned hard surface, with a cloth, mop, sponge, or coarse sprayer, thoroughly wetting surfaces. Surfaces must remain wet for at least one minute [60 seconds] followed by adequate draining and air drying. Do not rinse.

Precleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment can be sanitized by immersion for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

{or}

Immerse pre-cleaned glassware, dishes, silverware, cooking utensils and other similar size food processing equipment in a solution of *(insert appropriate dilution from box above here)* [or equivalent dilution] for at least 60 seconds. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

Prepare fresh sanitizing solution daily or more often if the use solution becomes diluted or soiled. For mechanical applications, use-solution may not be reused for sanitizing applications but may be reused for other purposes such as cleaning.

Apply to sink tops, counter tops, refrigerated storage and display equipment and other stationary surfaces by cloth, sponge [or] brush [or coarse spray].

TO SANITIZE FOOD PROCESSING EQUIPMENT, UTENSILS, AND OTHER FOOD CONTACT ARTICLES REGULATED BY 40 CFR 180.940 (a) [IN A THREE COMPARTMENT SINK]:

1. Scrape, flush, or presoak articles [whether mobile or stationary] to remove gross food particles and soil.
2. Thoroughly wash articles with an appropriate detergent or cleaner.
3. Rinse articles thoroughly with potable water.
4. Sanitize by immersing articles with a use-solution of *(insert appropriate dilution from box above here)* for at least 60 seconds. Articles too large for immersing must be thoroughly wetted by rinsing, spraying, or swabbing.
5. Remove immersed items from solution to drain and then air dry. Non-immersed items must also be allowed to air dry. Do not rinse.

Bardac 205M-14.08 can be used in accordance with the U.S. Public Health Service food service sanitization recommendations.

U.S. PUBLIC HEALTH SERVICE FOOD SERVICE SANITIZATION RECOMMENDATIONS

CLEANING AND SANITIZING: Equipment and utensils must be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

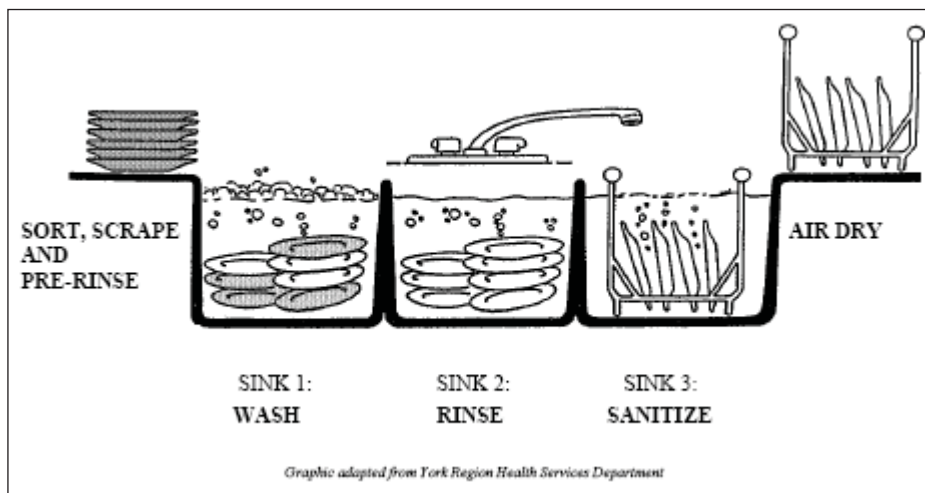
1. Thoroughly wash equipment and utensils in hot detergent solution.
2. Rinse utensils and equipment thoroughly with potable water.
3. Sanitize equipment and utensils by immersion in a use-solution of *(insert appropriate dilution from box above here)* for at least 60 seconds at a temperature of 75°F.
4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of [3/4 oz. of **Bardac 205M-14.08** per 4 – 5 1/2 gallons of water [0.14 – 0.19 oz. of **Bardac 205M-14.08** per gallon of water] [150 – 200 ppm active quat]] or [3/4 oz.- 2 oz. of **Bardac 205M-14.08** per 5 1/2 gallon of water [0.14 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [150 – 400 ppm active quat]] by rinsing, spraying or swabbing until thoroughly wet.
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 glasses whenever possible.
2. Wash with a good detergent or compatible cleaner.
3. Rinse with potable water.
4. Sanitize in a solution of *(insert a dilution of 200 ppm active or higher dilution from box above here)*. Immerse all utensils for at least two minutes or for 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 HFS 196, Appendix 7-204.11 of the Wisconsin Administrative Code (reference 40 CFR 180.940 (a)).

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



TO SANITIZE [SOFT SERVE] [FOOD] [AND] [FROZEN] [BEVERAGE] DISPENSING EQUIPMENT:

1. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
2. Fill equipment with a solution of *(insert appropriate dilution from box above here)* [or equivalent dilution].
3. Allow solution to remain in equipment for at least 60 seconds.
4. Drain thoroughly [and allow to air dry] before reuse. Do not rinse.

TO SANITIZE ICE MACHINES:

1. Turn off refrigeration.
2. Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing.
3. Apply a solution of (*insert appropriate dilution from box above here*) [or equivalent dilution] by mechanical spray, directly pouring, or by recirculating through the system.
4. Allow surfaces to remain wet or solution to remain in equipment for at least 60 seconds.
5. Drain thoroughly before reuse and allow to air dry.

TO SANITIZE SANITARY FILLING EQUIPMENT:

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of (*insert appropriate dilution from box above here*) [or equivalent dilution] for final washer and rinser applications. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse. Do not rinse.

TO SANITIZE BEER FERMENTATION AND STORAGE TANKS:

Wash equipment with a compatible detergent and rinse with potable water prior to sanitizing. Prepare a use-solution of (*insert appropriate dilution from box above here*) [or equivalent dilution] for mechanical or automated systems. Allow surfaces to remain wet for at least 60 seconds. Drain thoroughly and allow to air dry before reuse. Do not rinse.

WATERPROOF GLOVE SANITIZING DIRECTIONS

To prevent cross contamination into processing areas of food plants, waterproof gloves must be sanitized prior to entering or re-entering those areas. Remove gross contamination from gloves before sanitizing. Then place gloved hand in a use-solution of (*insert appropriate dilution from box above here*) [or equivalent dilution] for sixty seconds. Change the solution in the bath at least daily or more often if the solution appears visibly diluted or soiled.

SANITIZING – NON-POROUS GLOVED HANDS:

To prevent cross contamination into animal areas and the packaging and storage areas of food plants, dip, soak or spray pre-washed [plastic, latex or other synthetic rubber] gloved hands so that there is enough sanitizing solution to cover the gloved area. Do not let sanitizing solution come in contact with exposed skin. Make up the sanitizing solution by adding (*insert appropriate dilution from box above here*) [or equivalent dilution]. Dip, soak or spray in solution and allow gloved hands to remain wet for at least 60 seconds. No potable water rinse is allowed. Change the sanitizing solution in the bath at least daily or when solution appears dirty.

TO SANITIZE 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 [3/4 oz. of **Bardac 205M-14.08** per 4 – 5 1/2 gallons of water [0.14 – 0.19 oz. of **Bardac 205M-14.08** per gallon of water] [150 – 200 ppm active quat] or [3/4 oz.- 2 oz. of **Bardac 205M-14.08** per 5 1/2 gallon of water [0.14 – 0.37 oz. of **Bardac 205M-14.08** per gallon of water] [150 – 400 ppm active quat]]. The solution must be equal to or 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 must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs.

Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.

FOR CONTINUOUS TREATMENT OF CONVEYORS:

Remove gross food particles and excess soil by a pre-flush or pre-scrape. Wash with a good detergent or compatible cleaner. Rinse equipment thoroughly with potable water, then rinse equipment with a sanitizing solution. During processing, apply **Bardac 205M-14.08** at (*insert appropriate dilution from box above here*) [or equivalent dilution] to conveyors with [BRAND NAME] [MIKRO MASTER] [or other] suitable feeding equipment. Controlled volumes of sanitizer are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operation, coarse spray equipment, peelers, collators, slicers and saws with [BRAND NAME] [MIKRO MASTER] dispensed **Bardac 205M-14.08** solution of (*insert appropriate dilution from box above here*) [or equivalent dilution]. Conveyors and other equipment must be free of product when applying this coarse spray. Use (*insert appropriate dilution not less than 200 ppm AI either chosen from the box above here or an equivalent dilution*) in Wisconsin dairy processing facilities.

{For food processing or other facilities that have installed entryway sanitizing systems:}

ENTRYWAY SANITIZING SYSTEMS:

To prevent cross contamination from area to area, set the system to deliver [0.37 – 0.73 oz. per gallon of water] [1 – 2 oz. per 5 1/2 gallons of water] [400 – 800 ppm active] of sanitizing solution. The [spray] [foam] must cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor. Do not mix other foam additives to the sanitizing solution.

SHOE BATH SANITIZER DIRECTIONS:

To prevent cross-contamination into animal areas, [and the packaging and storage areas of food plants], shoe baths containing one inch of freshly made sanitizing solution must be placed at all entrances to buildings, and hatcheries, [and production and packaging rooms]. Scrape waterproof work [boots] [shoes] and place in a use-solution of 1 oz. of **Bardac 205M-14.08** per 5 1/2 gallons of water [or equivalent dilution] [200 ppm active] for 3 minutes prior to entering area. **[{This Optional Statement is Not for Use in California:}** If there is a heavy soil load or excessive traffic, place work [boots] [shoes] in a use solution of [0.37 – 0.73 oz. per gallon of water] [1 – 2 oz. per 5 1/2 gallons of water] [200 – 400 ppm active] for 60 seconds prior to entering area.] Change the solution in the bath at least daily or more often if the solution appears diluted or soiled.

SHOE FOAM SANITIZER DIRECTIONS:

To prevent cross-contamination into animal areas, and the packaging and storage areas of food plants. Apply a foam layer approximately 1/2 to 2 inches thick made from a solution of 2 to 3 oz. of **Bardac 205M-14.08** per 2 3/4 gallons of water [or equivalent dilution] [800 to 1200 ppm active], at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply the foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator or aerator. Scrape waterproof work [boots] [shoes]. Stand or walk through foamed area for 3 minutes prior to entering area. Foam area must be washed and foam replaced at least daily or more often if the foam appears visibly diluted or soiled.

{Note to reviewer: For Nonrefillable Containers, Label has Household and Residential Uses}

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Wrap [container] and put in trash or offer for recycling if available.

{or}

Store in original container in areas inaccessible to children. 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 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.

{Metal containers only:} DO NOT cut or weld metal containers.

{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.

{Note to reviewer: For Nonrefillable Sealed Containers: Packaging options can be in sealed containers or bottles designed for use dilution systems to reduce worker exposure to the concentrate. None of these can be triple rinsed because they are closed sealed containers. The following text will be used on these sealed container types:}

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. Wrap empty container and put in trash.

{Note to reviewer: For Refillable Containers – 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. Refillable container. Refill this container with *[this product]* only. Do not reuse this container for any other purpose.

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.

FINAL CONTAINER DISPOSAL

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container.

{Plastic or Metal Containers:} To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat this rinsing procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in sanitary landfill. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

{Metal containers only:} DO NOT cut or weld metal containers.

PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL

FOR DISINFECTION

*{Note to reviewer: the following will be used for 1/4 oz of concentrate:
MIX EACH PACKET WITH [1/2 GALLON] OF WATER}*

*{Note to reviewer: the following will be used for 1/2 oz of concentrate:
MIX EACH PACKET WITH [1 GALLON] OF WATER}*

*{Note to reviewer: the following will be used for 1 oz of concentrate:
MIX EACH PACKET WITH [2 GALLONS] OF WATER}*

*{Note to reviewer: the following will be used for 2 oz of concentrate:
MIX EACH PACKET WITH [4 GALLONS] OF WATER}*

{If other packet sizes are desired, new packet label will be identical and the only things that will vary are the net contents, amount of water to dilute with and ppm active quat. Those 3 items will have to match or be equivalent to the dilution chart that is shown on page 12.}

BARDAC 205M -14.08

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	4.224%
Dioctyl dimethyl ammonium chloride.....	1.690%
Didecyl dimethyl ammonium chloride.....	2.534%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.632%
Other [Inert] Ingredients	<u>85.920%</u>
Total.....	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER [PELIGRO]

See outer container for Precautionary Statements and Use directions

Disposal: Do not reuse packet. Wrap and put in trash.

EPA. Reg. No. 6836-278

EPA. Est. No. *(insert EPA Est. No. here)*

Net Contents:

Lonza Inc. 90 Boroline Road, Allendale, NJ 07401

[Not for retail sale]

SECONDARY CONTAINER LABEL

{Note to reviewer: When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements:}

BARDAC™ 205M-14.08

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	4.224%
Dioctyl dimethyl ammonium chloride	1.690%
Didecyl dimethyl ammonium chloride	2.534%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.632%
Other [Inert] Ingredients	85.920%
Total	100.000%

The product in this container is diluted as directed on the pesticide product label.

KEEP OUT OF REACH OF CHILDREN

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

Follow the directions for use on the pesticide label when applying this product.

EPA Reg. No. 6836-278

This container is not for the sale or distribution of the diluted product.

{Note to reviewer: The following are optional graphics and marketing language}

For Bag – In – Box Containers:

How to use this package:

This package is designed to be used with dilution control systems only. Open package and connect to dispense according to directions on box top.

Trigger Sprayers:

Fill bottle from dispenser.

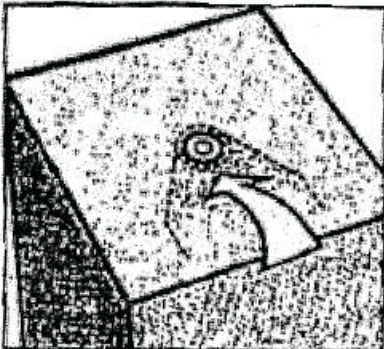
Apply to surfaces as specified in directions above.

Mop Buckets:

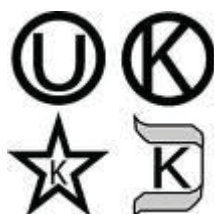
Fill bucket from dispenser.

Set up “Wet Floor” signs.

Mop floor surface as specified in directions above

OPENING INSTRUCTIONS 1. Position box with perforation up. 2. Press in circle. 3. Lift flap/tear along perforation. 4. Retrieve fitting on bag. 5. Remove clear dust-cap from bag fitting. 6. Twist dispenser connector onto bag fitting. 7. Place bag-in-box into position on dispenser shelf. 8. Close dispenser (if applicable).		INSTRUCCIONES PARA ABRIR 1. Ponga la caja con la perforación hacia arriba. 2. Empuje el círculo hacia adentro. 3. Levante la pestana arrancándola de la caja a lo largo de la perforación. 4. Saque el adaptador que está en la bolsa. 5. Quite la tapa transparente contra el polvo que tiene el adaptador de la bolsa. 6. Enrosque el conector desechador al adaptador. 7. Ponga la “bag-in-box” (bolsa en caja) en posición en el mostrador de despacho. 8. Cierre el despachador (si corresponde).
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{Note to reviewer. The following may be used only if the supplemental registrant has obtained a Kosher Certification.}



[Any Kosher Symbol such as:]

[Kosher]

{Note to reviewer: The following is optional text.}

www.[URL].com

{Note to Reviewer: The website URL may also be provided as a Quick Response (QR) code. Below is an example of a QR code that could appear on the final label.}



[Use your [smart]phone] [to] [and] [scan] [the] [this] [tag] [code] [to] [learn] [see] [more] [uses] [information]
[videos] [on how to use] [on] [for] [this product] [for] [how to] [tips][.]