## UP ED STATES ENVIRONMENTAL PROTEC IN AGENCY



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

DEC 1 5 2008

Ms. Georgia Anastasiou Agent for Lonza, Inc Lewis & Harrison 122 C Street, NW Suite 740 Washington, DC 20001

SUBJECT: Bardac 205M-50

EPA Registration No.: 6836-233 Amendment Date: July 2, 2008 EPA Receipt Date: July 11, 2008

Dear Ms. Anastasiou,

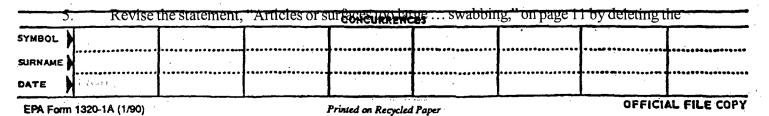
The following amendment submitted in connection with registration under FIFRA section 3(c)7 is acceptable with the conditions listed below.

• Add additional microorganisms, claims, use sites

#### **Conditions**

Revise the label as follows:

- 1. Under the "Precautionary Statements" on page 2, revise the second to last statement by incorporating the phrase, "...and before eating, drinking, chewing gum, or using tobacco."
- 2. Revise the 13<sup>th</sup> claim on page 3 by deleting "EPA."
- 3. Revise the last statement in the Mushroom Farms claim on page 9 by deleting the term, "should," and replacing it with the term, "must," so that it is in compliance with PR Notice 2000-5, Mandatory Labeling..
- 4. Revise the 1<sup>st</sup> statement in the 1<sup>st</sup> paragraph on page 11 by deleting the term, hazardous, and replace it with 'food poisoning." Also, delete "disease" which appears in the 3<sup>rd</sup> statement in this paragraph. The use of "hazardous" and "disease" are terms that imply heighten efficacy.



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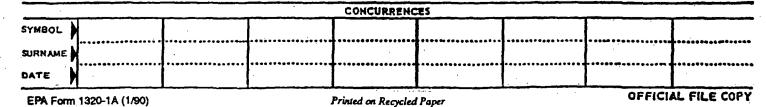
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term "should" and replacing it with, "must," such that the statement is in agreement with PR Notice 2000-5, Mandatory Labeling.

- 6. Revise "Personal Protection" and "Contact Time" statements associated with the HIV/HBV directions on page 14 by deleting the term, "should," and replace it with, "must," such that the statement is in agreement with PR Notice 2000-5, Mandatory Labeling.
- 7. Qualify "rollers" under the "Nail/Manicure Salon/Barber Instruments and Tools" directions on page 15 as a hard nonporous tool by stating "plastic" rollers.
- 8. Delete the "Sanitize Floor Drains in Food Processing Areas" directions on page 17 because the proposed directions are not appropriate for this type of claim. Efficacy data must be submitted to support this claim, and it is recommended that you schedule a pre-application meeting to discuss the requirements.
- 9. Revise the third paragraph under the "Sanitize Food Contact Surfaces" directions on page 19 by stating "Articles too large for immersing, apply a use solution of ... coarse sprayer." Delete the phrase, "or by immersion." Also, move the 6<sup>th</sup> paragraph under "Sanitize Food Contact Surfaces" directions on page 19 to appear after the third paragraph.
- 10. Revise the "Non-Porous Gloved Hands" directions on page 22 by deleting the phrase, "spreading of harmful organisms," and replace it with "cross contamination."
- 11. Delete the "Dairy Cow Application Directions" on page 22 because the ADBAC and DDAC REDs mandated that this use will no longer be supported on EPA product labels because it is a use under FDA's jurisdiction.
- 12. Revise the 5<sup>th</sup> statement under the "Poultry and Swine Premise" directions on page 24 by deleting the term, recommended, so it is in compliance with PR Notice 2000-5, Mandatory Labeling.
- 13. Any ADBAC containing product supporting fogging directions for animal housing facilities and food processing plants must be revised to comply with the mitigation measures addressed in the ADBAC RED. Therefore, revise "Fogging Device Hatchery Room" and "Fogging Device Incubator and Hatcher" sanitizing directions on page 25 by adding the statement, "wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus." Also, revise the last statement in each section that is in bold text as well as the second statement under "Note" to read:

"Under no circumstances will a room be entered by anyone within two hours of the actual fogging and a minimum of 4 air exchanges (ACH) per hour in the facility."

14. Revise the first statement under "Mushroom Farm Premise" directions and the last two statements under "Citrus Canker Disease Control" directions on page 27 by deleting the term, should, and replace it with "must."



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The "Final Container Disposal" instructions on page 31 are incomplete because they do 15. not indicate how to dispose of the container once it has been rinsed. Add the following statements, "Offer for recycling or reconditioning if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities."

#### **General Comments**

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

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Jacqueline McFarlane at (703)308-6416 or Velma Noble at (703) 308-6233.

Sincerely,

Velma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510P)

Enclosure: Stamped Label

CONCURRENCES SYMBOL

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

## BARDAC® 205M-50

Disinfectant - Sanitizer - Fungicide - Virucide\* - Deodorizer

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

For 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
  - · Salmonellacidal · Fungicidal · Virucidal\*

Active Ingredients:	
Octyl decyl dimethyl ammonium chloride	15.0%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium chloride	
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride	
Other Ingredients	50.0%
Total	

## KEEP OUT OF REACH OF CHILDREN

## DANGER PELIGRO

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

ACCEPTED with COMMENTS in EPA Letter Dated:

EPA Reg. No. 6836-233
EPA Est. No. (insert EPA Est. No. here)
Net Contents: (as indicated on container)

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6836-233 Manufactured by: Lonza Inc. 90 Boroline Road Allendale, NJ 07401

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 1 OF 34

## 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 gloves (rubber, chemical resistant) when handling. Avoid breathing spray mist. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

#### FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably 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.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 2 OF 34

#### (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-50

- 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 EPA's Sanitizer Test standards for non-food contact surface sanitizers. At 200 ppm active, Bardac 205M-50 is an effective one-step sanitizer by eliminating 99.9% of Staphylococcus aureus and Klebsiella pneumoniae in 60 seconds.
- meets AOAC Germicidal & Detergent standards for sanitizing previously cleaned food-contact surfaces.
- has been cleared under 40 CFR 180.940 (a) and (c) 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 – 400 ppm active).
- is a disinfectant, sanitizer, fungicide, virucide, deodorizer, bacteriostat 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 3/4 1 oz. per 19 1/2 gallons of water (150 200 ppm active).
- For use in [insert name of automated dilution system here] (automated) (dilution system).

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



(Any Kosher Symbol such as:)

(Kosher)

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 3 OF 34

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

**Bardac 205M-50** (Kills) (Eliminates) (Removes) (Destroys) avian influenza A (Turkey/Wisconsin) (H5N1) on pre-cleaned environmental surfaces

Bardac 205M-50 (Kills) (Eliminates) (Removes) (Destroys) [Insert pathogen or pathogens from lists on pages 9 - 11] on pre-cleaned environmental surfaces

Bardac 205M-50 (Kills) (Eliminates) (Removes) (Destroys) Germs) (Bacteria) (Viruses\*) (on precleaned environmental surfaces)

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. [Caution: Cleaning at the recommended 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-50** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 4 OF 34

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

#### Use Bardac 205M-50:

- 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.
- as a broad spectrum disinfectant in Ultrasonic Baths (Ultrasonic cleaning units).
- to sanitize and disinfect 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.
- 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.
- 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 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.

Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. **Bardac 205M-50** 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 may be used only if the supplemental registrant has obtained an NSF listing. Allowed on back or side panel only.)



(NSF Listed)
(Insert 6-Digit NSF Listing Number here)

3

## (Note to reviewer: The following is considered optional marketing language.) (AREAS OF USE:)

Use Bardac 205M-50 in:

Homes [Households] Kitchens Prisons Public facilities Public rest rooms  Dental offices Public rest rooms  Dental offices Schools Health Care Facilities Shower and bath areas Hospitals Salons [Beauty] [Tanning] [Mail] [Manicure] Medical Offices  Medical Offices  Medical Related facilities Camp grounds Nursing homes Play ground equipment Sick Rooms Day care centers Animal laboratories Nurseries Dairy farms Farms Bars Hog farms Beverage Plants Kennels Cafeterias Mushroom Farms Convenience stores Poultry farms Egg Processing Plants Food Preparation Areas Pet shops Food processing plants Turkey farms Food storage areas Institutional kitchens Restaurants (Front of House) Airplanes  USDA inspected food processing facilities Athletic facilities Barber shops Buses Business and office buildings Careger (Police) (EMS) (Fire) (Rescue) vehicles Prasilers (Train Cars) (Box cars) (Rail Cars) Institutional facilities Trailers Institutional facilities Trailers Institutional facilities Trains (Train Cars) (Box cars) (Rail Cars) Institutional facilities Trains (Train Cars) (Box cars) (Rail Cars) Institutional facilities Trains (Train Cars) (Box cars) (Rail Cars) Institutional facilities Trains (Train Cars) (Box cars) (Rail Cars) Institutions	Bathrooms	Locker rooms
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Institutions Transportation terminals		
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	Laundries	Trucks (Box Trucks)

## (Note to reviewer: The tollowing is considered optional marketing language.)

## (TYPES OF SURFACES:)

Use Bardac 205M-50 on washable hard, nonporous surfaces of:

Appliances, exteriors	Toilets
Bathroom fixtures	Toilet bowls
Bathtubs [fiberglass]	Toilet bowl surfaces
Cabinets	Tubs [Fiberglass]
Cages	Tiles, glazed
Chairs	Ultrasonic baths
Coils and drain pans of air conditioning and	Urinals
refrigeration equipment and heat pumps	Walls
Conductive flooring	Whirlpool [bathtubs] [tubs] [units]
Counters [Countertops]	
Countertop laminates	Beer fermentation and holding tanks
Desks	Beverage dispensing equipment
Doorknobs (and Handles)	Blenders
Floors	Bottling or premix dispensing equipment
Foot Spas	Chopping blocks, plastic and other
Garbage cans	nonporous
Highchairs	Cooking utensils
Kennel runs	Coolers
Microwave ovens, exteriors	Cutlery
(exterior surfaces of)	Cutting Boards, plastic and other nonporous
Outdoor [patio] furniture except cushions	Dishes
and wood frames	Eating Utensils
Refrigerators, exteriors	Food processors
(exterior surfaces of)	Food dispensing equipment
Refrigerated storage and display	Frozen Drink (Beverage) Machines
equipment	Glassware
Showers	Ice Chests
[Fiberglass] Shower stalls	Ice Machines
[Fiberglass] Sinks [bathroom] [kitchen]	Ice cream dispensing equipment [Soft Serve]
Sinks [bathroom] [kitchen]	Plastic Food Storage Containers
Stoves [stovetops]	Kitchen equipment
Tables, [Non-wooden picnic tables]	Refrigerator bins used for meat, fruit,
Tanning Beds	vegetables and eggs
Telephones	Silverware

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 7 OF 34

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

## (TYPES OF SURFACES:)

Use Bardac 205M-50 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

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 8 OF 34

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

#### Use Bardac 205M-50:

- 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-50 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).
- 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 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.

**Bardac 205M-50** 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-50** 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-50** should be limited to areas where compost and mushrooms are not present.

## (Note to reviewer: The to:/lowing is considered optional marketing language:)

Bardac 205M-50 is an effective sanitizer for use on food contact surfaces in 400 ppm hard water

(Note to reviewer: 150 ppm AI)

Escherichia coli

Staphylococcus aureus

Bardac 205M-50 at 1/2 oz. per 9 3/4 gallons of water is an effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 500 ppm hard water against:

(Note to reviewer: 200 ppm AI)

Campylobacter jejuni

(Community Associated) Methicillin-Resistant Staphylococcus

aureus - [CA-MRSA] [MRSA] (NRS384) (USA300)

(Community Associated) Methicillin-Resistant Staphylococcus

aureus - [CA-MRSA] [MRSA] (NRS123) (USA400)

Escherichia coli

Escherichia coli 0157:H7

Klebsiella pneumoniae

Listeria monocytogenes

Salmonella enterica

Shigella sonneii

Staphylococcus aureus -(Methicillin-Resistant [MRSA])

Vibrio cholerae

Yersinia enterocolitica

Bardac 205M-50 is an effective sanitizer for use on food contact surfaces in 1000 ppm hard water against: (Note to reviewer: 400 ppm AI)

Escherichia coli

Staphylococcus aureus

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

Regular, effective cleaning and sanitizing of equipment, utensils, and work or dining surfaces which could harbor hazardous 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 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 prevent cross-contamination, 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 should be thoroughly wetted or flooded by rinsing, spraying or swabbing.

Allow all sanitized surfaces to drain (and air dry).

**Bardac 205M-50** fulfills the criteria of Appendix F of the Grade "A" Pasteurized Milk Ordinances 1999 Recommendations of the U.S. Public Health Services in waters up to 500 ppm of hardness calculated as CaCO<sub>3</sub> when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

Bardac 205M-50 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-50 is effective against the following animal viruses:

Arkansas '99 [Infectious Bronchitis Virus]

Avian Infectious Bronchitis Virus

Avian Infectious Laryngotracheitis Virus

Avian Influenza Virus (Tur/Wis) (Turkey/Wisconsin)

Avian Influenza Virus (H5N1)

Canine Distemper Virus

Feline Calicivirus

Laryngotracheitis Virus

Marek's Disease Virus

Newcastle's Disease Virus

Pseudorabies Virus

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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### (Note to reviewer: The following is considered optional marketing language:)

**Bardac 205M-50** 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 )* 

Bardac 205M-50 kills [is effective against]:

(Bacteria):

Pseudomonas aeruginosa (Pseudomonas)

Staphylococcus aureus (Staph)-(Methicillin-Resistant-[MRSA])

Salmonella enterica (Salmonella)

Brevibacterium ammoniagenes [Brevibacterium]

Campylobacter jejuni [Campylobacter]

Escherichia coli [E. coli]

Escherichia coli pathogenic strain 0157:H7 [pathogenic E. coli]

Klebsiella pneumoniae [Klebsiella]

Listeria monocytogenes [Listeria]

\_(Community Associated) Methicillin-Resistant Staphylococcus

- aureus - [CA-MRSA] [MRSA] (NRS384) (USA300)

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

Pseudomonas cepacia [Pseudomonas]

Salmonella typhi [Salmonella]

Yersinia enterocolitica

(Viruses:)

- \*Adenovirus Type 5
- \*Adenovirus Type 7
- \*Hepatitis B Virus (HBV)
- \*Herpes Simplex Virus Type 1 (Herpes)
- \*Herpes Simplex Virus Type 2 (Herpes)
- \*Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)
- \*Influenza A2 / Hong Kong [Influenza] [Flu] Virus
- \* Norwalk Virus (Norovirus (Feline Calicivirus)
- \*SARS Associated Human Coronavirus
- \*Vaccinia Virus (Pox Virus)

(Fungi:)

Aspergillus niger

Trichophyton mentagrophytes (Athlete's Foot Fungus) (A Cause of Ringworm) (A Cause of Ringworm of the foot)

Bardac 205M-50 is effective against Citrus Canker Disease (Xanthomonas axonopodis pv. citri).

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 12 OF 34

#### **DIRECTIONS FOR USE**

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

Dilution:	
Disinfection (1:1100)	1 1/4 oz. per 10 3/4 gallons of water
	1/8 oz. per gallon of water
	(450 ppm active quat)
Sanitizer (1:1248)	1 oz. per 9 3/4 gallons of water
	(400 ppm active quat)
Sanitizer (1:2496)	
	(200 ppm active quat)
Sanitizer (1:3328)	1/2 oz. per 13 gallons of water
	(150 ppm active quat)

#### **DISINFECTION / \*VIRUCIDAL/FUNGICIDAL DIRECTIONS:**

Add 1 1/4 oz. of **Bardac 205M-50** per 10 3/4 gallons 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)

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. 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, exteriors of 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 recommended required.

(or)

For heavily soiled areas, preclean first.

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

or

This product is not for use on medical device surfaces.

\*KILLS HIV AND HBV 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).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

**PERSONAL PROTECTION:** Clean up should always be done wearing protective gloves, gowns, masks and eye protection.

**CLEANING PROCEDURE:** Blood and other body fluids containing HIV-1 or HBV must be thoroughly cleaned from surfaces and objects before application of **Bardac 205M-50**.

**CONTACT TIME:** Leave surfaces wet for 10 minutes with a 1 1/4 oz. of **Bardac 205M-50** per 10 3/4 gallons of water use solution (or equivalent dilution). **DISPOSAL OF INFECTIOUS MATERIAL:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 14 OF 34

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**For mold and mildew**, 1 ½ oz. of **Bardac 205M-50** per 10 3/4 gallons 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.

#### NON-ACID TOILET BOWL AND URINAL DISINFECTANT DIRECTIONS:

Remove heavy soil prior to disinfection.

From concentrate: Add 1/8 oz. of BARDAC 205M-50 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 1/4 oz. per 10 3/4 gallons 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.

**FOR USE ON FINISHED FLOORS:** To limit gloss reduction use **BARDAC 205M-50** at 1 1/4 oz. per 10 3/4 gallons of water. Apply with a damp mop or autoscrubber.

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

Mix 1 1/4 oz. of **Bardac 205M-50** per 10 3/4 gallons of water (or equivalent dilution) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, 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-50** to disinfect hard nonporous non-critical instruments / objects compatible with Ultrasonic cleaning units.

Pour fresh use-solution of 1 1/4 oz. of **Bardac 205M-50** per 10 3/4 gallons 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]] [FOOT SPAS] DISINFECTION DIRECTIONS:

After using [whirlpool [bath] [unit]]-[foot spa], drain and fill with a use solution of 1 1/4 oz. of Bardac 205M-50 per 10 3/4 gallons 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] [foot spa] 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 1 1/4 oz. of Bardac 205M-50 per 10 3/4 gallons 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.

#### TO SANITIZE NON-FOOD CONTACT SURFACES:

Add 1/2 oz. of **Bardac 205M-50** per 9 3/4 gallons of water (or equivalent dilution) 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. Avoid breathing spray.

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

Treated surfaces must remain wet for 1 minute. 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 / SALON INSTRUMENTS AND TOOLS:** Immerse precleaned barber / salon instruments and tools (such as combs, brushes, razors, scissors, blades and manicure instruments) in a use-solution of 1/2 oz. of **BARDAC 205M-50** per 9 3/4 gallons of water (or equivalent dilution) for at least 60 seconds (one minute). 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:

Use 0.6 ounces per 100 pounds of dry weight fabric. Dilute the appropriate amount of **Bardac 205M-50** 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.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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#### TO SANITIZE FLOOR DRAINS IN FOOD PROCESSING AREAS:

Use on accessible floor drain openings, removable caps and rings, catch baskets and exposed surfaces that are regularly cleaned. Before sanitizing pre-clean and scrub all surfaces, rinse thoroughly and apply 1/2 oz. of Bardac 205M-50 per 13 gallons of water [or equivalent dilution] by sprayer or immersion to thoroughly wet all surfaces.

For sprayer applications, cover or remove all food products. Use a coarse [foam] spray device and apply 6-8 inches from surface. Do not breathe spray. Treated surfaces must remain wet for 1 minute prior to reuse.

Prepare fresh solution daily or more often if solution is used for immersion and becomes visibly diluted, cloudy or soiled.

(Note to reviewer. On a final printed label, only one of the following auution rates will be used in the sanitization sections below )

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

"[1 oz. of BARDAC 205M-50 per 26 gallons of water (150 ppm active quat)]"

O

"[1 oz. of BARDAC 205M-50 per 19 1/2 gallons of water (2 oz. of Bardac 205M-50 per 39 gallons of water) (200 ppm active quat)]"

or

"[1 oz. of **BARDAC 205M-50** per 9 ¾ gallons of water (4 oz. of **Bardac 205M-23** per 39 gallons of water) (400 ppm active quat)]"

01

"[1 oz. of BARDAC 205M-50 per 19 1/2 - 26 gallons of water (150 - 200 ppm active quat)]"

or

"[1 oz. of BARDAC 205M-50 per 9 3/4 – 26 gallons of water (150 – 400 ppm active quat)]"

or

"[1 oz. of **BARDAC 205M-50** per 9 3/4 – 19 1/2 gallons of water (2 – 4 oz. of **Bardac 205M-50** per 39 gallons of water) (200 – 400 ppm active quat)]"

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 18 OF 34

#### 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.

Apply a use solution of *[insert appropriate dilution here]* (or equivalent dilution) to the pre-cleaned hard surface, with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces. Surfaces must remain wet for at least one minute (60 seconds) followed by adequate draining and air drying. Do not rinse.

Prepare fresh 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.

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

## 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 clean water.
- 4. Sanitize by immersing articles in a use-solution of [insert appropriate dilution here] (or equivalent dilution) (150 400 ppm active) for at least 60 seconds. Articles too large for immersing should be thoroughly wetted by rinsing, spraying, or swabbing.
- 5. Remove immersed items from solution to drain and then air dry. Non-immersed items should also be allowed to air dry. Do not rinse.

**BARDAC 205M-50** 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.

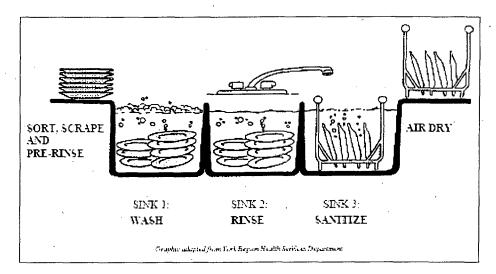
- 1. Thoroughly wash equipment and utensils in hot detergent solution.
- 2. Rinse utensils and equipment thoroughly with clean water.
- 3. Sanitize equipment and utensils by immersion in a use solution of [insert appropriate dilution here] (or equivalent dilution) for at least 60 seconds at a temperature of 75°F.
- 4. For equipment and utensils too large to sanitize by immersion, apply a use-solution of [insert appropriate dilution here] (or equivalent dilution) 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 clean 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 code.
- 5) Place sanitized utensils on a rack or drain board to air-dry.

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)



BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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#### TO SANITIZE [SOFT SERVE] [FUOD] [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 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 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 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 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.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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#### WATERPROOF GLOVE SANITILING 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] 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 the spreading of harmful organisms 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]. 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 [insert appropriate dilution here] (or equivalent dilution). 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-50 at [insert appropriate dilution from box above here] to conveyors with 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 MIKRO MASTER dispensed Bardac 205M-50 solution of [insert appropriate dilution from box above here]. Conveyors and other equipment must be free of product when applying this coarse spray. Use [insert appropriate dilution from box above here. Must be 200 ppm Al Minimum] in Wisconsin dairy processing facilities.

**DAIRY COW APPLICATION DIRECTIONS:** The udders, flanks, and teats of dairy cows can be washed with a solution of *[insert appropriate dilution here]* (or equivalent dilution) (150 - 400 ppm active). Use a fresh towel for each cow. Avoid contamination of wash solution by dirt and soil. Do not dip used towel back into wash solution. When visibly dirty, discard and provide fresh solution.

Bardac 205M-50 [kills] [is effective against] (the following animal viruses):

[Animal Viruses:]

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

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

[VETERINARY], [ANIMAL CARE] and [ANIMAL LABORATORY] FACILITIES/ [ZOOS] / [PET SHOPS] / [KENNELS] 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 ½ oz. of **Bardac 205M-50** per 10 ¾ gallons 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. Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 4. Saturate surfaces with a use-solution of 1 ½ oz. of **Bardac 205M-50** per 10 ¾ gallons of water [or equivalent dilution] for a period of 10 minutes. Wipe or allow to air dry.
- 5. Immerse all animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure.
- 6. 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.
- 7. Ventilate buildings, animal enclosures, [vehicles] and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 23 OF 34

#### POULTRY AND SWINE PREMISE DISINFECTION 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 1/4 oz. of **Bardac 205M-50** per 10 3/4 gallons of water. Saturate surfaces with the recommended 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, 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 1/4 oz. per 10 3/4 gallons 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 water and **Bardac 205M-50**. Use 1 1/4 oz. per 10 3/4 gallons of water. Apply use solution to treat all vehicles. Leave all 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 1/4 oz. per 10 3/4 gallons of water. Saturate all surfaces with use solution and scrub to loosen all soils. Surfaces must remain wet for 10 minutes, then thoroughly rinsed with potable water before operations are resumed.

#### FOGGING DEVICE HATCHERY KOOM SANITIZER DIRECTIONS:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of the room to be treated. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix 1 gal. of **Bardac 205M-50** per 20 gal. of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting in maximum output, for one minute for each 4000 cubic feet of space in the room. **Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed)**.

#### FOGGING DEVICE INCUBATOR AND HATCHER SANITIZER DIRECTIONS:

Mix 1 gallon of **Bardac 205M-50** per 10 gallons of water. Fog 3 - 8 ounces of this into setters and hatchers immediately after transfer. Repeat daily in setters and every 12 hours in hatchers. Discontinue hatcher treatments at least 24 hours prior to pulling the hatch. It is acceptable to fog setters and hatchers with a 1 ounce per gallon solution of **Bardac 205M-50** on an hourly or every other hour basis. If this is done, fog for 30 - 90 seconds once per hour or once every two hours. When fogging is completed, ventilate buildings, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse. **Do not allow people to contact or breathe this fog and do not enter until the fog has settled (30 - 60 minutes after fogging is completed)**.

**NOTE:** The fog generated is irritating to the eyes, skin and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has settled (30 - 60 minutes after fogging is completed). If the building must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTING FOR ROOM AND MACHINE.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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#### **ENTRYWAY SANITIZING SYSTEMS:**

To prevent cross contamination from area to area, set the system to deliver 1 - 2 oz. per 9 3/4 gallon of water (2 - 4 oz. per 19 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 should be placed at all entrances to buildings (and hatcheries). Scrape waterproof work (boots) (shoes) and place in a use-solution of 1/2 oz. of Bardac 205M-50 per

9 3/4 gallons of water (or equivalent dilution) for 60 seconds prior to entering area. (If there is a heavy soil load or excessive traffic place work (boots) (shoes) in a use-solution of 1 - 2 oz. per 9 3/4 gallon of water (2 - 4 oz. per 19 gallons of water) (400 – 800 ppm active quat.)). 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 - 3 oz. of **Bardac 205M-50** per 9 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 60 seconds 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.

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.) EPA REG. NO. 6836-233 EPA DRAFT 11-19-08 PAGE 26 OF 34



#### MUSHROOM FARM PREMISE USE:

**Site Preparation:** The first step in any on-going sanitation program should 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 1/4 oz. of BARDAC 205M-50 per

10 3/4 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 2 1/2 oz. of **BARDAC 205M-50** per 10 3/4 gallons 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 CANKER 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 1:250 use-dilution (5 oz. of **BARDAC 205M-50** per 9 3/4 gallons of water or equivalent dilution) (2000 ppm active quat) for a period of 10 minutes. Allow to air dry. All surfaces that come in contact with food or crop must be rinsed with potable water before reuse. To prevent the spread of Citrus Canker Disease by this artificial means of transportation, treatments are made by trigger spraying, dipping or brushing. Clothing should be either rinsed or laundered before reuse. Footwear should be rinsed before reuse.

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

#### STORAGE AND DISPOSAL

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

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

(or)

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

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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(Note to reviewer: For Nonrefillable Containers, Container is one gallon or less, Label has uses <u>other than</u> Household and Residential)

#### STORAGE AND DISPOSAL

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

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

(or)

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

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

#### STORAGE AND DISPOSAL

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

#### Pesticide Storage:

Do not store on side. Avoid creasing or impacting of side walls.

#### **Pesticide Disposal:**

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

#### **Container Disposal:**

Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. (*Plastic Containers:*) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. 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 tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

(Metal Containers:) Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. 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 tripled rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations. DO NOT cut or weld metal containers. (For Bag in Box Containers:) 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 Refillable Containers, Container is over one gallon:)

#### 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. Cleaning before refilling is the responsibility of the refiller.

#### Pesticide Storage:

Do not store on side. Avoid creasing or impacting of side walls.

#### 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

Clean container promptly after emptying. 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 remaining contents from container for use according to use directions and triple rinse promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times.

#### (For Bag-in-Box Containers:)

#### 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:

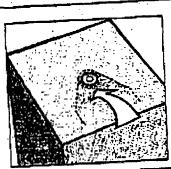
Fill bucket from dispenser.

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 flaphear along perforation.
- 4. Retrieve fitting on bag.
- 5. Remove clear dust-cap from bag
- fining. 6. Twist dispenser connector pitto bag
- fitting. 7. Place bag-in-box into position on dispenser shelf.
- 8. Close dispensor (if applicable).



### INSTRUCCIONES PARA ABRIR

- 1. Ponge la caje con la perforacion hacta arriba.
- 2. Empujo el cucuto inscia adentro.
- 2. Levente la postora arrancandola de la caja e to largo de la perforación.
- 4. Secun el sespondor que esto en la boiss.
- 5. Quite la laps marapareres contra el polyo
- que dere el assiptador de la boisa. Entração el conectador despachatica al
- eda pro dec. 7. Ponga to "bag-in-hox" (botto en caja) en posición en el mostrador de despecho.
- 5. Cierre el despeciador (si corresponde).

#### PACKET LABEL TO BE USED WITH MASTER CONTAINER LABEL

#### FOR DISINFECTION

Note to reviewer: the following will be used for 1 1/4oz of concentrate:
MIX EACH PACKET WITH 10 3/4 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 13.]

## **BARDAC 205M-50**

EPA. Reg. No. 6836-233

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

#### **Net Contents:**

Active ingredients:	
Octyl decyl dimethyl ammonium chloride	15.0%
Dioctyl dimethyl ammonium chloride	
Didecyl dimethyl ammonium chloride	
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride	20.0%
Other Ingredients	50.0%
Total	

### 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.

Lonza Inc. 90 Boroline Road, Allendale, NJ 07401

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#### SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary container label will be used only when the product is diluted at 1 1/4 oz. per 10 3/4 gallons of water (450 ppm AI) or less))

## BARDAC® 205M-50

EPA Reg. No. 6836-233

Active Ingredients:	
Octyl decyl dimethyl ammonium chloride	15.0%
Dioctyl dimethyl ammonium chloride	6.0%
Didecyl dimethyl ammonium chloride	
Alkyl (C <sub>14</sub> , 50%; C <sub>12</sub> , 40%; C <sub>16</sub> , 10%) dimethyl benzyl ammonium chloride	
Other Ingredients	50.0%
Total	100.0%

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

## KEEP OUT OF REACH OF CHILDREN

## **CAUTION**

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**Caution.** 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

BARDAC 205M-50 (Note To Reviewer: Language in ( ) is considered optional or interchangeable.)
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