

6836-266

7/15/2004

1/15

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 15 2004

Mr. Robert Sloan
Lonza Inc
17-17 Route 208
Fair Lawn, NJ

Subject: Bardac 205M-10
EPA Registration No. 6836-266
Amendment Date: January 20, 2004
EPA Receipt Date: January 21, 2004

Dear Mr. Sloan,

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

- Addition of Organisms

Conditions

Revise the label as follows:

1. Page 1: Bold the subheadings (If swallowed/If in eyes/If on skin or clothing) under "First Aid."
2. Page 2: Delete the claim, "state of the art," it implies heighten efficacy.
3. Page 3: Specify that the picnic tables and Outdoor (patio) furniture are hard nonporous surfaces by stating *Non-wooden picnic tables and "Outdoor (patio) furniture except cushions and wood frames.*
4. Page 5: Since Ringworm is caused by several different fungi, revise the claim to read as "*Trichopyton mentagrophytes* (A cause of ringworm) or (A cause of ringworm **of the foot**).
5. Page 9: Under "Entryway Sanitizing Systems" and "Shoe Bath Sanitizer" directions revise the claims, "to prevent cross-contamination of harmful organisms from area to area," and "by deleting "of harmful organisms."

CONCURRENCES

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

6. Page 10: Under "Shoe Bath and Shoe Foam Sanitizer directions," revise the phrase, "to prevent tracking of harmful bacteria into animal areas" to state "to prevent cross contamination into animal areas..."
7. Page 10: Bold the subheadings under "Container Disposal."
8. Typographical Errors
 - Page 4: Revise product name in the 6th claim on left panel to read "Bardac 205M-10"
 - Page 5: Change the *E. coli* pathogenic strain to read "O157:H7."
 - Page 7: Revise the 2nd use dilution rate on the right panel to read "0.25 oz. of Bardac 205M-10 per gallon of water."
 - Page 9: Under Citrus Canker Disease Control," revise phrase "though treatment" to read "through treatment."

Data Summary

Data Requirement	Means of Support	Status
Initial Virucidal Effectiveness Using Duck Hepatitis B Virus	Submitted study, MRID 461494-02	Acceptable
Confirmatory Virucidal Effectiveness Test Using Duck Hepatitis B Virus	Submitted study, MRID 461494-03	Acceptable
Virucidal Effectiveness - Human Immunodeficiency Virus	Submitted study, MRID 461494-04	Acceptable
Virucidal Efficacy Test- Adenovirus Type 5	Submitted study, MRID 461494-05	Acceptable
Virucidal Efficacy of Disinfectant- Infectious Laryngotracheitis Virus	Submitted study, MRID 461494-06	Acceptable

According to Agency letter dated February 25, 2004, the MRID Nos. 460296-02 and 460296-03 that support a food contact sanitizing claim against *E. coli* and *S. aureus* in 1000 ppm hard water was acceptable. Also, the bacterial stability data in MRID Nos. 457036-03 and 460296-01 was accepted.

In regard to the *Vibrio cholerae* claim, MRID No. 460296-01, the February 25th letter denied the claim based on a need for additional information on the purity and sterility controls. However, the data was previously accepted for EPA Registration No. 6836-289. The Agency will conditionally accept the *V. cholerae* claim provided you address the need for additional information by December, 2004.

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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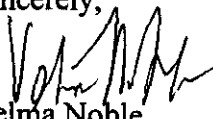
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) 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 or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label
Efficacy Data Evaluation

CONCURRENCES

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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 or absorbed through the skin. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber, chemical resistant) when handling. 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.

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-10

Disinfectant - Sanitizer – Fungicide – Virucide* –
Deodorizer

Effective in the presence of 5% serum contamination

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
- Salmonellacidal • Fungicidal • Virucidal*

Active Ingredients:

Octyl decyl dimethyl ammonium chloride.....	3.00%
Dioctyl dimethyl ammonium chloride.....	1.20%
Didecyl dimethyl ammonium chloride.....	1.80%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride.....	4.00%
Other (Inert) Ingredients.....	90.00%
Total.....	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

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

EPA Reg. No. 6836-266

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

Net Contents: *(as indicated on container)*

ACCEPTED manufactured by:
LONZA ~~with comments~~ 208, Fair Lawn, NJ 07410
in EPA Letter Dated:

JUL 15 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No **6836-266**

(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-10:

- 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, 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-10** 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 by the FDA in 21 CFR §178.1010 for use on food processing equipment, utensils and other food-contact articles (at a concentration of 150 – 400 ppm active).
- is a state-of-the-art 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 0.2 – 0.5 oz. per gallon (150 – 400 ppm active).

Cross-contamination is of major (housekeeping) (food safety) concern. **Bardac 205M-10** has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

Use Bardac 205M-10:

- 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 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.

Soiled and contaminated fabrics are of major housekeeping concern in hospitals, institutions, hotels, restaurants and schools. **Bardac 205M-10** 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.)

(AREAS OF USE:)

Use Bardac 205M-10 in:

Bathrooms
Homes (households)
Kitchens

Dental offices
Health Care Facilities
Hospitals
Medical Offices
Nursing homes

Day care centers
Nurseries

Bars
Beverage Plants
Cafeterias
Convenience stores
Egg Processing plants
Food processing plants
Food preparation areas
Food storage areas
Institutional kitchens
Restaurants
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)

Camp grounds
Play ground equipment

Animal laboratories
Dairy farms
Farms
Hog farms
Kennels
Mushroom farms
Poultry farms
Pet animal quarters
Pet shops
Turkey farms
Zoos

Airplanes
Airports
Boats
Buses
Campers
Cars
Emergency vehicles
Mobile homes
Ships
Taxis
Trailers
Trains
Transportation terminals

(TYPES OF SURFACES:)

Use Bardac 205M-10 on washable hard, nonporous surfaces of:

Appliances, exteriors
Bathroom fixtures
Bathtubs
Cabinets
Cages
Chairs
Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
Conductive flooring
Counters (countertops)
Countertop laminates
Desks
Doorknobs
Fiberglass bathtubs
Fiberglass sinks
Floors
Garbage cans
Highchairs
Kennel runs
Microwave ovens, Exterior Surfaces of
Outdoor furniture,
Refrigerators, Exterior Surfaces of
Refrigerated storage and display equipment
Showers
Shower stalls
Sinks (bathroom, kitchen)
Stoves (stovetops)

Tables, (picnic tables)
Telephones
Toilets
Toilet bowls
Toilet bowl surfaces
Tubs
Tiles, glazed
Ultrasonic baths
Urinals
Walls
Whirlpool bathtubs

Beer fermentation and holding tanks
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
Glassware
Ice Chests
Kitchen equipment
Refrigerator bins used for meat, fruit, vegetables and eggs
Silverware
Slurpy Machines
Tupperware®

Other hard nonporous surfaces made of:
Formica®
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: The following is considered optional marketing language:)

Use Bardac 205M-10:

- 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-210** 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.

Bardac 205M-10 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-10** 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-10** should be limited to areas where compost and mushrooms are not present.

Bardac 205M-10 is effective against Citrus Canker Disease (*Xanthomonas axonopodis* pv. *citri*) at 2000-ppm active quat.

Bardac 205M-10 (kills) (is effective against):

- Arkansas '99 (Infectious Bronchitis Virus)
- Avian Infectious Bronchitis Virus
- Avian Influenza Virus
- Canine Distemper Virus
- Laryngotracheitis Virus
- Marek's Disease Virus
- Newcastle's Disease Virus
- Pseudorabies Virus

Bardac 205M-10 at 1/5 oz. per gallon of water (or equivalent dilution) is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active and 400 ppm hard water against:

- Escherichia coli
- Staphylococcus aureus

Bardac 205M-10 at 1/4 oz. per gallon of water (or equivalent dilution) is an effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 500 ppm hard water against:

- Campylobacter jejuni
- Escherichia coli
- Escherichia coli 0157:H7
- Klebsiella pneumoniae
- Listeria monocytogenes
- Salmonella choleraesuis
- Shigella sonnei
- Staphylococcus aureus
- Yersinia enterocolitica
- Vibrio cholerae

Bardac 205M-10 at (1/2 oz. per gallon of water) (1 oz per 2 gallons of water) (or equivalent dilution) is an effective sanitizer for use on food contact surfaces in 60 seconds at 400 ppm active and 1000 ppm hard water against:

- Escherichia coli
- Staphylococcus aureus

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-10 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 CaCO₃ when evaluated by the AOAC Germicidal and Detergent Sanitizer Method.

Bardac 205M-10 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-10 is a Hospital Disinfectant (at 1:213 dilution) (450 ppm active) (3 oz. per 5 gallons of water), 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-10 (kills) (is effective against):

(Bacteria):

- Pseudomonas aeruginosa (Pseudomonas)
- Staphylococcus aureus (Staph)
- Salmonella choleraesuis (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)
- Pseudomonas cepacia (Pseudomonas)
- Salmonella typhi (Salmonella)
- Yersinia enterocolitica

(Viruses):

- *Adenovirus Type 5
- *Hepatitis B Virus (HBV)
- *Herpes Simplex Type 1 (Herpes)
- *Herpes Simplex Type 2 (Herpes)
- *Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)
- *Influenza A2 / Hong Kong (Influenza)
- *Vaccinia (Pox Virus)

- Arkansas '99 (Infectious Bronchitis Virus)
- Avian Infectious Bronchitis Virus
- Avian Influenza Virus
- Canine Distemper Virus
- Laryngotracheitis Virus
- Marek's Disease Virus
- Newcastle's Disease Virus
- Pseudorabies Virus

(Fungi):

- Trichophyton mentagrophytes (Athlete's Foot Fungus)
(Cause of Ringworm)

DILUTION:

Disinfection (1:213).....	3 oz. per 5 gallons of water	(450 ppm active quat)
Sanitizer (1:256).....	½ oz. per gallon of water	(2½ oz. per 5 gallons of water)
.....	(400 ppm active quat)
Sanitizer (1:512).....	¼ oz. per gallon of water	(1¼ oz. per 5 gallons of water)
.....	(200 ppm active quat)
Sanitizer (1:640).....	1/5 oz. per gallon of water	(1 oz. per 5 gallons 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 DIRECTIONS:

Add 3 oz. of **Bardac 205M-10** per 5 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.

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(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) 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)

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-10**.

CONTACT TIME: Leave surfaces wet for 10 minutes with a 3 oz. per 5 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.

NON-ACID TOILET BOWL AND URINAL DISINFECTANT DIRECTIONS:

Remove heavy soil prior to disinfection.

From concentrate: Add 0.6 oz. of **Bardac 205M-10** 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 3 oz. per 5 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-10** at 3 oz. per 5 gallons of water. Apply with a damp mop or autoscrubber.

SALON (BARBER) INSTRUMENTS AND TOOLS DISINFECTION (BACTERICIDE) / VIRUCIDE / FUNGICIDE DIRECTIONS:

Mix 3 oz. of **Bardac 205M-10** per 5 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-10** to disinfect hard nonporous non-critical instruments / objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 3 oz. of **Bardac 205M-10** per 5 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 DISINFECTION DIRECTIONS:

After using whirlpool unit, drain and fill with a use solution of 3 oz. of **Bardac 205M-10** per 5 gallons of water to just cover the intake valve. Start the pump to circulate the solution. Wash down the 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 unit has been thoroughly disinfected, drain the solution from the unit and rinse disinfected surfaces with fresh water. Repeat for heavily soiled units.

TO SANITIZE NON-FOOD CONTACT SURFACES:

Add ¼ oz. of Bardac 205M-10 per gallon 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 ¼ oz. of BARDAC 205M-10 per gallon 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.

TO SANITIZE LAUNDRY (AGAINST ODOR CAUSING BACTERIA):

Use 3 ounces per 100 pounds of dry weight fabric. Dilute the appropriate amount of Bardac 205M-10 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.

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

"[1 oz. of BARDAC 205M-10 per 4 - 5 gallons of water (0.20 - 0.25 oz. of Bardac 205M-10 per gallon of water) (150 - 200 ppm active quat)]"

or

"[1 oz. of BARDAC 205M-10 per 4 gallons of water (0.20 Bardac 205M-10 per gallon of water) (200 ppm active quat)]"

or

"[1 oz. of BARDAC 205M-10 per 2 - 5 gallons of water (0.20 - 0.50 oz. of Bardac 205M-10 per gallon of water) (150 - 400 ppm active quat)]"

TO SANITIZE FOOD CONTACT SURFACES, FOOD PROCESSING EQUIPMENT AND OTHER HARD SURFACES IN FOOD PROCESSING LOCATIONS, DAIRIES, RESTAURANTS AND BARS:

For sanitizing 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.

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TO SANITIZE FOOD PROCESSING EQUIPMENT, UTENSILS, AND OTHER FOOD CONTACT ARTICLES REGULATED BY 21CFR § 178.1010:

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 with a use-solution of *[insert appropriate dilution here]* 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.

TO SANITIZE 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 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.

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.

BARDAC 205M-10 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 appropriate dilution here]* (or equivalent dilution). 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 Section HFS 196.13 of the Wisconsin Administrative Code.

(For food processing or other facilities that have installed entryway sanitizing systems :)

ENTRYWAY SANITIZING SYSTEMS:

To prevent cross contamination of harmful organisms from area to area, set the system to deliver (0.50 – 1 oz. per gallon of water) (1 – 2 oz. per 2 gallons of water) (400 – 800 ppm active) of sanitizing solution. The (spray) (foam) should 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.

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). 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.

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 3 oz. of **BARDAC 205M-10** per 5 gallons 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 6 oz. of **BARDAC 205M-10** per 5 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.

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

For cleaning and disinfecting hard nonporous surfaces of equipment used for animal food or water; utensils, instruments, cages, crates kennels, stables and catteries.

1. Remove all animals and feed from premises, vehicles, and enclosures.
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 other feeding and watering appliances.
4. Thoroughly clean surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with a use-solution of 3 oz. of **BARDAC 205M-10** per 5 gallons of water (or equivalent dilution) for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.
7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated (feeding and watering appliances), (feed racks, mangers, troughs, automatic feeders, fountains and waterers) with soap or detergent, and rinse with potable water before reuse.]

FARM PREMISE DISINFECTION DIRECTIONS

1. Remove all animals and feed from premises, vehicles, and enclosures.
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 other feeding and watering appliances.
4. Thoroughly clean surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with a use-solution of 3 oz. of **BARDAC 205M-10** per 5 gallons of water (or equivalent dilution) for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure.
7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated (feeding and watering appliances), (feed racks, mangers, troughs, automatic feeders, fountains and waterers) with soap or detergent, and rinse with potable water before reuse.]

CITRUS CANKER DISEASE CONTROL:

For prevention of Citrus Canker Disease though 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 1:50 use-dilution (4½ oz. of **BARDAC 205M-10** per 1¾ 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.

POULTRY AND SWINE PREMISE DISINFECTION DIRECTIONS:

1. Remove all animals and feeds from premises, vehicles and enclosures such as coops, and crates.
2. 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.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with a use-solution of 3 oz. of **Bardac 205M-10** per 5 gallons of water (or equivalent dilution). for a period of 10 minutes.
6. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, cars, trucks, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
8. 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 3 oz. per 5 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-10**. Use 3 oz. per 5 gallons of water. Apply use solution to treat all vehicles. 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 3 oz. per 5 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.

SHOE BATH SANITIZER DIRECTIONS: To prevent tracking harmful organisms (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 ¼ oz. of **Bardac 205M-10** per gallon 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 ½ - 1 oz. per gallon of water (2½ - 5 oz. per 5 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.

(Note to reviewer: If container is one gallon or less, the following Storage and Disposal statements will be used:)

STORAGE AND DISPOSAL

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

(Note to reviewer: If container is greater than one gallon, the following Storage and Disposal statements will be used:)

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:

(Plastic Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities by burning. If burned, stay out of smoke.

(Metal Containers:) Triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(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:

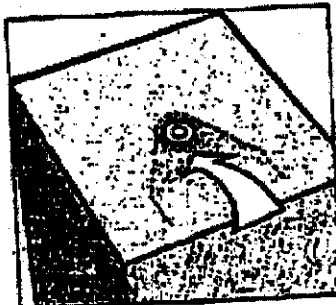
Fill bucket from dispenser.

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 flap over 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 pestaña arrancadola 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 pozo que tiene el adaptador de la bolsa.
6. Enrosque el conector dispensador al adaptador.
7. Ponga la "bag-in-box" (nota en caja) en posición en el mezclador de despaqueo.
8. Cierre el dispensador (si corresponde).