6836-303 a

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Page 1712

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 13 2003

Ms. Ana Rodriguez-Koster Agent for Lonza Lewis & Harrison 122 C Street. NW Suite 740 Washington. DC 20001

Subject:

Bardac 205M-5.2

EPA Registration No. 6836-303 Amendment Date: August 21, 2002 EPA Receipt Date: August 22, 2002

Dear Ms. Rodriguez-Koster,

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

- Addition of Bacterial Stability Claim
- Addition of organisms

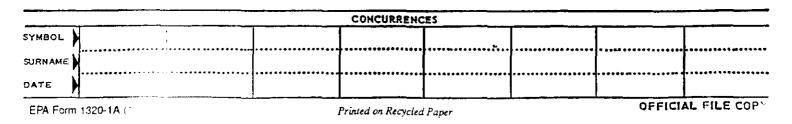
Conditions

- 1. Page 2: Delete the claims, "inhibits bacterial growth on moist surfaces" and "residual bacteriostat."
- 2. Page 3: Delete the use site, "Laundries." There are no use directions to support a laundry sanitization claim.
- 3. Page 4: The food contact sanitizer claims in the second column will need to be revised by specifying the use solution; it should read as follows:

Bardac 205M-10 at 3/8 oz. per gallon of water is an effective sanitizer for use on food contact surfaces in 60 seconds at 150 ppm active and 400 ppm hard water.

Bardae 205M-10 at $\frac{1}{2}$ oz. per gallon of water is effective sanitizer for use on food contact surfaces in 60 seconds at 200 ppm active and 500 ppm hard water.

4. Page 5: Delete the "bacterial stability of use dilution" claim.



- 5. Page 6: Revise the "Non-Food Contact Surfaces" directions to state "sanitize *precleaned* hard, nonporous surfaces."
- 6. Page 7: Delete the directions for "sanitize food contact surfaces" because the directions are an incomplete version of the "sanitize food processing equipment and other hard surfaces in food processing locations, dairies, restaurants, and bars."
- 7. Page 8: Under Veterinary Practice/Animal Care/Animal Laboratory, add the statement, "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." The statement should appear after the contact time sentence.
- 8. Page 10: The Hatcheries, Vehicles, and Dressing Plant directions must be revised by adding the use solution, "Use 2 1/4 oz. per 2 gallons of water."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label 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) 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)

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 rubber gloves 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

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-5.2

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:

rights high actorical	
Octyl decyl dimethyl ammonium chloride	1.560%
Dioctyl dimethyl ammonium chloride	0.624%
Didecyl dimethyl ammonium chloride	0.936%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	2.080%
Inert Ingredients9	4.800%
Total	

KEEP OUT OF REACH OF CHILDREN

DANGER **PELIGRO**

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

EPA Reg. No. 6836-303

EPA Est. No. (insert EPA Est. No. here) Net Contents: (as indicated on container)

Manufactured by: LONZA INC., 17-17 Route 208, Fair Lawn, NJ 07410

> ACCEPTED with COMMATHES in Ul Marior Doesd:

FEB 1 3 2003

(Note To Reviewer: Language in () is considered optional or interchangeable). BARDAC 205111

(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-5.2:

- 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.
- inhibits bacterial growth on moist surfaces
- deodorizes by killing microorganisms that cause offensive odors.
- is a complete, chemically balanced disinfectant, sanitizer and (residual bacteriostat) 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-7.5 is an effective one-step sanitizer by eliminating 99.9% of Staphylococcus aureus and Klebsiella pneumoníae 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)

Cross-contamination is of major (housekeeping) (food safety) concern. Bardac 205M-7.5 has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

Use Bardac 205M-5.2

- 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.

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roughered Lader SPA Reg. No. 6836-343

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

(AREAS OF USE:)

Use Bardac 205M-5.2 in:

Bathrooms

Homes (households)

Kitchens

Dental offices 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

Camp grounds

Play ground equipment

Animal laboratories

Dairy farms Hog farms Kennels

Mushroom farms
Poultry farms
Pet animal quarters

Pet shops Turkey farms

Zoos

Airplanes Boats Buses Campers Cars

Emergency vehicles

Mobile homes

Ships Taxis Trailers Trains

Transportation terminals

(TYPES OF SURFACES:)

Use Bardac 205M-5.2 on washable

hard, nonporous surfaces of:

Appliances
Bathroom fixtures

Bathtubs Cabinets Cages

Chairs

Coils and drain pans of air conditioning and refrigeration equipment and

heat pumps

Conductive flooring Counters (countertops)

Desks
Doorknobs
Floors
Garbage cans
Highchairs
Kennel runs
Microwave ovens
Outdoor furniture,
Refrigerators

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

Coolers

Cutting Boards, plastic and other

nonporous

Dishes
Eating Utensils
Food processors

Glassware lce Chests

Kitchen equipment Refrigerator bins used for meat, fruit,

vegetables and eggs

Silverware Slurpy Machines Tupperware®

Other hard nonporous surfaces made

or: Fiberglass Formica®

Glazed ceramic

Glazed enameled surfaces

Glazed porcelain

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

ACCEPTED with COMMENTS in EPA Letter Dated:

FEB 1 3 2003

BARDAC 205M-5.2 Under the Federal Insecticide,
(Note To Reviewer: Language in () is considered optional or interchangeable.)
EPA REG. NO. 6836-303

PAGE 3 OF 10

amencled, for the perticide, registered under EPA Reg. No. 6836-303

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

Use Bardac 205M-5.2:

- 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-5.2 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-5.2 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-5.2 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-5.2 should be limited to areas where compost and mushrooms are not present.

Bardac 205M-5.2 is effective against Citrus Canker Disease (Xanthomonas axonopodis pv. citri) at 2000-ppm active quat.

Bardac 205M-5.2 is effective against:
Avian Infectious Bronchitis Virus
Avian Influenza Virus
Canine Distemper Virus
Marek's Disease Virus
Newcastle's Disease Virus
Pseudorabies Virus
Arkansas '99 (Infectious Bronchitis Virus)

Bardac 205M-5.2 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-5.2 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 sonneii Staphylococcus aureus Yersinia enterocolitica

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.

Bardac 205M-5.2 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. ACCEPTED

with COMMENTS in EPA Letter Dated:

EEB I 3 2003

BARDAC 205M-5 1 (No EPA REG, NO. 6536-303 EPA LABEL AMEN D MENT 8-21-02

(Note To Reviewer: Language in () is considered optional or interchangeable.)

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

Bardac 205M-5.2 is a concentrated one-step (Hospital) disinfectant that is effective against a broad spectrum of bacteria, is virucidal*, fungicidal and eliminates odorcausing bacteria when used as directed.

Bardac 205M-5.2 is a Hospital Disinfectant at (1:113 dilution) (450 ppm active) (2½ oz. per 2 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-5.2 kills:

(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:)

- *Herpes Simplex Type 1 (Herpes)
- *Herpes Simplex Type 2 (Herpes)
- *Influenza A2 / Hong Kong (Influenza)
- *Vaccinia (Pox Virus)

(Fungi:)

Trichophyton mentagrophytes (Athlete's Foot Fungus)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 1 3 2003

Under the Federal Insecticide, Pangloids, and Redendoide Act as amended, for the peruoide, registered under EFA Reg. No

	21/4 oz. per 2 gallons of water (450 ppm active quat)
Sanitizer (1:128)	1 oz. per gallon of water (400 ppm active quat)
Sanitizer (1:256)	
Sanitizer (1:48)	3% oz. per gallon of water(150 ppm active quat)

DIRECTIONS FOR USE

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

DISINFECTION / VIRUCIDAL*/FUNGICIDAL DIRECTIONS: Add 21/4 oz. of Bardac 205M-5.2 per 2 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.

(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.

Prepare a fresh solution daily or more often if the use solution becomes visibly diluted or soiled.

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

For heavily soiled areas, a preliminary cleaning is recommended.

6836-303

BARDAC 205M-5.2 (No EPA REG. NO. 6836-303 EPA LABEL AMENDMENT 8-21-02

(Note To Reviewer: Language in () is considered optional or interchangeable.)

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be

This product is not to be used as a terminal sterilant / highlevel 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 highlevel disinfection.

This product is not for use on medical device surfaces.

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

Remove heavy soil prior to disinfection.

From concentrate: Add 1% oz. of Bardac 205M-5.2 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 21/4 oz. of Bardac 205M-5.2 per 2 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 21/4 oz. of Bardac 205M-5.2 per 2 gallons of water. Apply with a damp mop or autoscrubber.

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

Mix 21/4 oz. of Bardac 205M-5.2 per 2 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-5.2 to disinfect hard nonporous non-critical instruments / objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 21/4 oz. of Bardac 205M-5.2 per 2 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 21/4 oz. of Bardac 205M-5.2 per 2 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 ½ oz. of Bardac 205M-5.2 per gailon of water (or equivalent dilution) to sanitize hard, nonporous surfaces. Apply sanitizer use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces. For heavily soiled areas, a preliminary cleaning is recommended.

For sprayer applications, use a coarse spray device. Spray 6 - 8 inches from surface; rub with brush, sponge or cloth. Avoid breathing spray.

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 ½ oz. of BARDAC 205M-5.2 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 noncontaminated receptacle. Prolonged soaking may cause damage to metal instruments.

> ACCEPTED with COMMENTS in EPA Letter Dated:

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the perficide, registered under EPA Reg. No. 6836-303

BARDAC 205M-5.2 (Note To Reviewer: Language in () is considered optional or interchangeable.) EPA REG. NO. 6836-303 PAGE 6 OF 10

EPA LABEL AMENDMENT 8-21-02

TO SANITIZE FOOD CONTACT SURFACES:

Use % - ½ oz. of BARDAC 205M-5.2 per gallon of water (150 - 200 ppm active quat) (or equivalent dilution) for sanitizing of precleaned hard nonporous food-contact surfaces.

Apply, recommended use-dilution with a cloth, sponge, coarse sprayer, or by immersion, thoroughly wetting surfaces. Treated surfaces must remain wet for one minute. Allow to air dry. Do not rinse.

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.

Sanitize dishes, silverware, glasses, cooking utensils and other similar size food processing equipment by immersion. Prepare a fresh solution for each use. For mechanical applications, use-solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

TO SANITIZE 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 % - % oz. of BARDAC 205M-5.2 per gallon of water (150 – 200 ppm active quat) (or equivalent dilution) to the precleaned 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 visibly 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 $\frac{3}{6} - \frac{1}{2}$ oz. of BARDAC 205M-5.2 per gallon of water (150 – 200 ppm active quat) (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 21CFR § 178.1010:

- 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.
- Sanitize by immersing articles with a use-solution of ³/₈ - 1 oz. of BARDAC 205M-5.2 per gallon of water (150 - 400 ppm active) for at least 60 seconds. Articles too large for immersing should be thoroughly wetted by rinsing, spraying, or swabbing.
- 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 $\frac{3}{8}$ $\frac{1}{2}$ oz. of **BARDAC 205M-5.2** per gallon of water (or equivalent dilution) (150 200 ppm active quat).
- 3. Allow solution to remain in equipment for at least 60 seconds.
- 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 $\frac{3}{6}$ - $\frac{1}{2}$ oz. of **BARDAC 205M-5.2** per gallon of water (or equivalent dilution) (150 – 200 ppm active quat) 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 $\frac{3}{6}$ - $\frac{1}{2}$ oz. of **BARDAC 205M-5.2** per gallon of water (or equivalent dilution) (150 –200 ppm active quat) 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

FEB 1 3 2003

Under the Federal Insecticide,
Fundicide, and Rodenticide Act as
amended, for the periode,
registered under EPA Reg. No. 4836 - 303

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 usesolution of \% - \% oz. of BARDAC 205M-5.2 per gallon of water (or equivalent dilution) (150 – 200 ppm active quat). The solution must be equal to or warmer than the eggs, but not to exceed 130°F. Wet eggs thoroughly and allow to drain. Eggs sanitized with this product shall be subjected to a potable water rinse only if they are to be broken immediately for use in the manufacture of egg products. Eggs must be reasonably dry before casing or breaking. The solution must not be re-used for sanitizing eggs. Note: Only clean, whole eggs can be sanitized. Dirty, cracked or punctured eggs cannot be sanitized.

BARDAC 205M-5.2 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

- 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 % - ½ oz. of BARDAC 205M-5.2 per gallon of water (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 3/8 - 1/2 oz. of BARDAC 205M-5.2 per gallon of water (or equivalent dilution) by rinsing, spraying or swabbing until thoroughly wet.
- Allow sanitized surface to drain and air dry. Do not

WISCONSIN STATE BOARD OF HEALTH **DIRECTIONS FOR EATING ESTABLISHMENTS**

- 1) Scrape and pre-wash utensils and glasses whenever
- 2) Wash with a good detergent or compatible cleaner.
- 3) Rinse with clean water.
- 4) Sanitize in a solution of % ½ oz. of BARDAC 205M-5.2 per gailon of water (150 - 200 ppm active quat). 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-

NOTE: A clean potable water rinse following sanitization is not permitted under Section HFS 196.13 of the Wisconsin Administrative Code.

DAIRY COW APPLICATION DIRECTIONS: The udders. flanks, and teats of dairy cows can be washed with a solution of 3/8 - 1/2 oz. of BARDAC 205M-5.2 per gallon of water (or equivalent dilution) (150 - 200 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.

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

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables and catteries. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 1/4 oz. of Bardac 205M-5.2 per 2 gallons of water (or equivalent dilution) for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

FARM PREMISE USE:

Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of 2 1/4 oz. of Bardac 205M-**5.2** per 2 gallons of water (or equivalent dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

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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 21/4 oz. of Bardac 205M-5.2 per 2 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 4½ oz. of BARDAC 205M-5.2 per 2 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 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 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 1:25 usedilution (5 oz. of BARDAC 205M-5.2 per gallon 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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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 21/4 oz. of Bardac 205M-5.2 per 2 galions of water (or equivalent dilution). Saturate surfaces with the disinfecting solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings, cars, trucks, coops, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub treated feed racks, 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. 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 high pressure water and Bardac 205M-5.2. 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. 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, shoe baths containing one inch of freshly made sanitizing solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots and place in a use-solution of ½ oz. of Bardac 205M-5.2 per gallon of water (200 ppm active quat) (or equivalent dilution) for 60 seconds prior to entering area. Change the solution in the bath at least daily or more often if the solution appears visibly 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

FEB 1 3 2003

Under the Foderal Insecticide,
Pingicide, and Rodenticide Act as
among ad, for the pericide,
registered under EPA Reg. No. 4856-303