UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 13 2004

Mr. Robert Sloan Lonza, Inc 17-17 Route 208 Fair Lawn, NJ 07410

Subject:

Bardac 205M-1.30

EPA Registration No. 6836-277 Amendment Date: November 12, 2003 EPA Receipt Date: November 17, 2003

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 Bacterial Stability Claim
- Addition of Organisms

Conditions

Revise the label as follows:

- 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: Since this product is for residential use as well as institutional/commercial/industrial, the surfaces for "refrigerator and microwave ovens" must be revised to state "exterior surfaces of refrigerator and microwave ovens (residential use only)."
- 4. 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.
- 5. 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).

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 7. Page 8: Under "Entryway Sanitizing Systems," revise the phrase, "to prevent cross-contamination of harmful organisms from area to area" by deleting "of harmful organisms."
- 7. Page 10: Under "Shoe Bath Sanitizer" directions, revise the phrase, "to prevent tracking of harmful bacteria into animal areas" to state "to prevent cross contamination into animal areas..."
- 8. Page 10: Bold the subheadings under "Storage and Disposal."
- 9. Typographical Errors
 - On page 2, left column 14th claim, revise the phrase, "chemically balanced disinfectant, sanitizer that provides..." to read "chemically balanced disinfectant and sanitizer that provides...."
 - Page 9, Revise the 1st statement under the "Citrus Canker Disease Control" directions by stating "For prevention of Citrus Canker Disease *through* treatment...."

Acceptable Data

Data Requirement	Means of Support	Status
AOAC Sanitizing Action of Disinfectrants -Vibrio Cholerae	Submitted study, MRID 460296-01	Acceptable
AOAC Sanitizing Action of Disinfectrants - E. coli	Submitted study, MRID 460296-02	Acceptable
AOAC Sanitizing Action of Disinfectrants - S. choleraesuis	Submitted study, MRID 46029603	Acceptable
AOAC Use Dilution Test Confirmatory - Bacterial Stability Claim	Submitted study, MRID 46029604	Acceptable

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.

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.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Sincerely,

Welma Noble

Product Manager (31)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure:

Stamped Label

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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 (rubber, chemical resistant) 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 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.

ACCEPTED with COMMENTS in EPA Letter Dated:

MAY 1 3 2004

Under the Federal Insecticide,
Pungicide, and Rodenticide Act as
amended, for the posticide,
registered under EPA Reg. No. 6836-277

BARDAC® 205M-1.30

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	0.390%
Dioctyl dimethyl ammonium chloride	0.156%
Didecyl dimethyl ammonium chloride	0.234%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%)	
dimethyl benzyl ammonium chloride	0.520%
Other Ingredients	98.700%
Total	100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

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

EPA Reg. No. 6836-277

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

(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-1.30:

- 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-1.30 is an effective one-step sanitizer (by eliminating 99.9% of) (against) 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 1 1/2 – 4 oz. per gallon of water (150 – 400 ppm active).

Cross-contamination is of major (housekeeping) (food safety) concern. Bardac 205M-1.30 has been formulated to aid in the reduction of cross-contamination not only in hospitals, but in schools, institutions, and industry.

Use Bardac 205M-1.30:

- 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.

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

(AREAS OF USE:)

Use Bardac 205M-1.30 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

Locker rooms

Motels

Prisons

Public facilities

Public rest rooms

Schools

Shower and bath areas

(Beauty) Salons

Camp grounds

Play ground equipment

BARDAC 205M-1.30

EPA REG. NO. 6836-277 EPA DRAFT LASEL 11/12/03 Animal (life science) 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-1.30 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

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

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: Language in () is considered optional or interchangeable.)

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

Use Bardac 205M-1.30:

- 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-1.30 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-1.30 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-1.30 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-1.30 should be limited to areas where compost and mushrooms are not present.

Bardac 205M-1.30 is effective against Citrus Canker Disease (Xanthomonas axonopodis pv. citri) at 2000ppm active quat.

Bardac 205M-1.30 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-1.30 at 1 1/2 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 against:

> Escherichia coli Staphylococcus aureus

Bardac 205M-1.30 at 2 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 sonneii Staphylococcus aureus Vibrio cholerae Yersinia enterocolitica

Bardac 205M-1.30 at 4 oz. per gallon of water 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 foodcontact 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

Allow all sanitized surfaces to drain and air dry.

BARDAC 205M-1.30 (Note To Reviewer: Language in () is considered optional or interchangeable.) EPA REG. NO. 6836-277 EPA DRAFT LABEL 11/12/03

Bardac 205M-1.30 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.

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

Bardac 205M-1.30 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-1.30 is a Hospital Disinfectant at (1:28 dilution) (450 ppm active) (4 1/2 oz. per gallon 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-1.30 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)
(Cause of Ringworm)

Dilution:	
Disinfection (1:28)	4 1/2 oz. per gallon of water
***************************************	(450 ppm active quat)
Sanitizer (1:32)	
	(400 ppm active quat)
Sanitizer (1:64)	
	(200 ppm active quat)
Sanitizer (1:85)	
	(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 4 1/2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution) to disinfect hard, nonporous surfaces.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging materials must be removed from the room or carefully protected.

When used on surfaces in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities, this product is an effective fungicide against Trichophyton mentagrophytes (the athlete's foot fungus)

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.

(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)

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.

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 4 1/2 oz. of Bardac 205M-1.30 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 4 1/2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution) to exposed surfaces including under the rim with a cloth, mop, sponge or sprayer. Brush or swab thoroughly, then allow to stand for 10 minutes and flush.

FOR USE ON FINISHED FLOORS: To limit gloss reduction use 4 1/2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution). Apply with a damp mop or autoscrubber.

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

Mix 4 1/2 oz. of Bardac 205M-1.30 per gallon 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-1.30 to disinfect hard nonporous non-critical instruments / objects compatible with Ultrasonic cleaning units. Pour fresh use-solution of 4 1/2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution) directly into bath chamber. Preclean soiled objects. Place objects into unit and operate for a minimum of 10 minutes, according to manufacturer's use directions. Remove objects and rinse with sterile water (sterile water for injection), or allow to air dry. Prepare a fresh solution for each use.

After using whirlpool unit, drain and fill with a use solution of 4 1/2 oz. of **Bardac 205M-1.30** per gallon of water (or equivalent dilution) 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 2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution) (200 ppm active) to sanitize precleaned hard, nonporous surfaces. Apply sanitizer use-solution with a cloth, mop, sponge, sprayer or by immersion, thoroughly wetting surfaces.

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

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

Treated surfaces must remain wet for 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 2 oz. of BARDAC 205M-1.30 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.

WHIRLPOOL BATH DISINFECTION DIRECTIONS:

(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-1.30 per 1/2 – 2/3 gallons of water (1 1/2 – 2 oz. of Bardac 205M-1.30 per gallon of water) (150 – 200 ppm active qual)]"

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"[1 oz. of BARDAC 205M-1.30 per 1/2 gallon of water (2 oz. Bardac 205M-1.30 per gallon of water) (200 ppm active quat)]"

or

"[1 oz. of BARDAC 205M-1.30 per 1/4 – 2/3 gallons of water (1 1/2 – 4 oz. of Bardac 205M-1.30 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 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 *[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 21CFR § 178.1010:

- Scrape, flush, or presoak articles (whether mobile or stationary) to remove gross food particles and soil.
- 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] (or equivalent dilution) 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:

- Wash equipment with a compatible detergent and ninse with potable water prior to sanitizing.
- 2. Fill equipment with a solution of *[insert appropriate dilution here]* (or equivalent dilution).
- 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 *[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-1.30 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.
- Rinse utensils and equipment thoroughly with clean water.
- 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.
- 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.
- Allow sanitized surface to drain and air dry. Do not rinse

WISCONSIN STATE BOARD OF HEALTH DIRECTIONS FOR EATING ESTABLISHMENTS

- 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.
- Place sanitized utensils on a rack or drain board to airdry.

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 (4-8 oz. per gallon of water) (8-16 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.

(Note to reviewer: "Veterinary Practice..." and "Farm Premise" directions are almost identical, so the two can either be separated into 2 paragraphs or combined into one if a supplemental registrant wants:)

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

Of

FARM PREMISE DISINFECTION DIRECTIONS

- 1. Remove all animals and feed from premises, vehicles, and enclosures.
- Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals.
- 3. [For "Veterinary Practice...": Empty all feeding and watering appliances.] [For "Farm Premise Use" 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 4 1/2 oz. of Bardac 205M-1.30 per gallon 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.
- 7. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.
- **8.** [For "Veterinary Practice..." Thoroughly scrub all treated feeding and watering appliances with soap or detergent, and rinse with potable water before reuse. [For "Farm Premise Use", Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.]

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 4 1/2 oz. of Bardac 205M-1.30 per gallon of water (or equivalent dilution). Apply use solution with a cloth, mop, sponge, sprayer or by immersion to thoroughly wet the surfaces. Treated surfaces must remain wet for 10 minutes. Wipe or allow to air dry. For heavily soiled areas, preclean first. Prepare a fresh solution for each use or more often if solution becomes visibly diluted, clouded or soiled.

For Heavy Duty Cleaning: When greater cleaning is desired, use 9 oz. of BARDAC 205M-1.30 per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

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

CITRUS 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 carr be applied to trucks, attached trailers and field harvesting equipment including cargo area, wheels, tires, undercarriage, hood, roof, fenders, and any other 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 1:6.5 use-dilution (19 3/4 oz. of **BARDAC 205M-1.30** 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.

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 4 1/2 oz. of Bardac 205M-1.30 per callon 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. Use 4 1/2 oz. **Bardac 205M-1.30** per gallon of water. Leave all treated surfaces wet for 10 minutes or more. Allow to air dry.

Vehicles:

Clean all vehicles including mats, crates, cabs, and wheels with water and Bardac 205M-1.30. Use 4 1/2 oz. Bardac 205M-1.30 per gallon 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 4 1/2 oz. Bardac 205M-1.30 per gallon 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 2 oz. of Bardac 205M-1.30 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 4 - 8 oz. per gallon of water (20 - 40 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. 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:

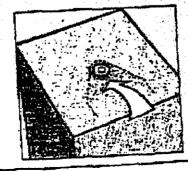
Fill bucket from dispenser.

Set up "Wet Floor" signs.

Mop floor surface as specified in directions above

OPENING INSTRUCTIONS

- Position box with perforation up.
- 2. Press in circle.
- 3. Lift depiteer along perforation.
- 4. Recrieve String on bag.
- 5. Remove clear dust-cap from bag
- ficino. Twist dispenser connector catto bag
- 7. Place bag-in-box iran position on
- dispenser shelf.
- 8. Class dispensar (if applicable).



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BARDAC 205M-1.30 EPA REG. NO. 6836-277 EPA DRAFT LABEL 11/12/03 (Note To Reviewer: Language in () is considered optional or interchangeable.)

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