

47371-93

10/3/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OCT - 3 2003

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Robert J. Sloan
H&S Chemicals Division
Lonza, Inc.
17 - 17 Route 208
Fair Lawn, N.J. 07410

SUBJECT: July 11, 2003 Application Amendment
M-2205 Farm Disinfectant/Sanitizer
EPA Registration 47371-93

Dear Mr. Sloan:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is conditionally acceptable.

Under Environmental Hazards, add "This pesticide is toxic to fish" to the beginning of warning.

On page 2, move paragraph above Directions for Use to beginning of section For Disinfecting.

At end of directions for Tuberculocidal add: The recommended use solution is prepared fresh for each use then discarded.

Fix typo on page 4 on left panel, change second 3 to 5 and on right panel change first 4 to 3.

In summary, you have revised the First Aid statement, the precautionary statements, and the Storage and Disposal statements.

If you have any questions regarding this letter, please contact Tom Luminello of my staff at (703) 308-8075.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert S. Brennis".

Robert S. Brennis

Product Manager (32)

Regulatory Management Branch II

Antimicrobial Division (7510-C)

Enclosure

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER Causes irreversible eye damage and skin irritation. Wear protective eyewear (goggles, safety glasses or face shield) and protective gloves (rubber or chemical resistant) when handling. Harmful if swallowed or inhaled. Avoid breathing vapors. Avoid contact with skin, eyes, or clothing. 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. Measures against circulatory shock, respiratory depression and convulsions may be needed.

(For 5 gallon & larger)

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.

add:
This pesticide is toxic
to fish,

M-2205 FARM DISINFECTANT / SANITIZER

Active Ingredient:

Iodine*1.75%

Other Ingredients:.....98.25%

Total100.00%

*From nonylphenoxy poly (ethyleneoxy) ethanol and polyethoxy polypropoxy polyethoxy ethanol-iodine complexes.

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 47371-93

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

Net Contents (insert container size here)

H&S Chemicals Division
c/o Lonza Inc.
17-17 Route 208
Fair Lawn, New Jersey 07410

ACCEPTED
WITH COMMENTS
IN EPA letter dated

OCT - 3 2008

47371-93

For use in poultry and turkey farms, life science animal cages, veterinary clinics, hospitals, nursing homes, medical and dental offices, dairies, federally inspected meat and poultry plants, and food processing equipment.

DISINFECTANT: (1:256) 1/2 oz. per gallon of water

AOAC USE-dilution Test

Effective against *Pseudomonas aeruginosa*,
Staphylococcus aureus, *Salmonella choleraesuis*1:256

AOAC Tuberculocidal Activity Test

Effective against *Mycobacterium tuberculosis* var. bovis strain BCG 1:256

Virucidal Qualification Test

Effective against Polio Virus Type I..... **1:256**

SANITIZER: (1:704)1 ounce per 5 ½ gallons of water

AOAC Available Chlorine Germicidal Equivalent Concentrate

Effective against Salmonella typhi and Staphylococcus aureus 1:704

For use on pre-cleaned, hard, nonporous surfaces such as floors, walls, metal surfaces, and glazed porcelain surfaces.

DIRECTIONS FOR USE

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

FOR DISINFECTING: Remove gross filth and heavy soil deposits. Thoroughly wet surfaces with 1 ounce per 2 gallons of water for a minimum contact time of 10 minutes in a single application. Can be applied by with a cloth, mop, sponge, coarse trigger sprayer or by soaking. Wipe dry with a clean cloth or sponge or allow to air dry.

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

Rinse all surfaces that come in contact with food such as countertops, appliances, tables and stovetops with potable water before reuse. Do not use on utensils, glassware and dishes as a disinfectant.

Tuberculocidal at a 1:256 dilution in the presence of 400 ppm synthetic hard water (calculated as CaCO_3) and moderate amounts of organic soils (5%) for a contact time of 10 minutes at 20°C on hard, non-porous, inanimate surfaces. Follow disinfection directions. *Recommended use solution is*

porous, inanimate surfaces. Follow disinfection directions. } The recommended use solution is prepared fresh for each use then
(Note to reviewer: Only One of the following two discards statements will be used:)

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

or
This product is not for use on medical device
surfaces.

FOR SANITIZING POULTRY DRINKING WATER, DILUTION: Use 1 ounce per 11 gallons of water (12 ½ ppm titratable iodine). Regular use helps keep the waterers free of slime and minerals.

DAIRY USE: The udders, flanks, and teats of dairy cows can be sanitized by washing with a solution of 1 ounce in 5 ½ gallons of warm water. Do not rinse. Use a fresh towel for each cow. Avoid contamination of sanitizing solution by dirt and soil. Do not dip used towel back into sanitizing solution. Prepare a fresh solution daily or, if solution becomes visibly dirty, discard and provide fresh solution.

ACCEPTED
WITH COMMENTS
In EPA Letter dated
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[illegible]

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FOR SANITIZING: Remove gross food particles and soil by a pre-flush, or pre-scrape and when necessary, presoak treatment. Use 1 ounce per 5 ½ gallons of water for a minimum contact time of 1 minute. Apply to sink tops, countertops, refrigerated storage, display equipment, and other stationary, hard surfaces by cloth or brush. **Do not rinse after sanitizing.** Surfaces must be adequately drained before contact with food so that little or no residue remains. Allow to air dry.

For mechanical operations, the prepared use solution may not be reused for sanitizing but may be used for other purposes such as cleaning. For manual operations, a fresh sanitizing solution must be prepared daily, or more often if the solution becomes diluted or soiled.

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.

FOR USE IN FOOD PROCESSING PLANTS: For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment, and other hard surfaces. Wash and rinse all articles thoroughly with a compatible detergent and rinse with potable water before sanitizing. Then apply a solution of 1 ounce in 5 ½ gallons of water for a contact time of 1 minute. Drain thoroughly. Do not rinse. Allow to air dry.

RESTAURANT AND BAR USE: Wash dishes, glassware, silverware, and cooking utensils with detergent. Rinse thoroughly with potable water. Then immerse in a solution of 1 ounce per 5 ½ gallons of water for a contact time of 1 minute to provide 25 ppm of titratable iodine. Drain thoroughly. Do not rinse. Allow to air dry.

FOOD AND BEVERAGE SANITIZATION PROCEDURES

BEER AND SOFT DRINK PLANTS: Wash and rinse all articles thoroughly with a compatible detergent and rinse with potable water before sanitizing. Drain thoroughly and fill equipment with 25 ppm sanitizing solution (1 ounce per 5 ½ gallons of water). Just before resuming operation, drain the equipment thoroughly. Do not rinse. Allow to air dry.

When changing soft drink flavors, rinse system well with water. Flush with 25 ppm sanitizing solution for at least 1 minute. Drain thoroughly. Allow to air dry. Do not rinse after sanitizing.

SANITIZING BOTTLES AND CANS: Wash and rinse all articles thoroughly with a compatible detergent and rinse with potable water before sanitizing. Proportion into the final rinse of the container washer 25 ppm titratable iodine. Use 1 ounce per 5 ½ gallons of water for a minimum contact time of one minute. The surfaces must be adequately drained before contact with food so that little or no residue remains. Do not rinse after sanitizing. Allow to air dry.

SANITIZING STORAGE TANKS: Wash and rinse all articles thoroughly with a compatible detergent and rinse with potable water before sanitizing. After cleaning, use a 25 ppm (1 ounce per 5 ½ gallons of water) solution for sanitizing beer fermentation and holding tanks. Use solution can be used in conjunction with automated clean-in-place systems. Do not rinse after sanitizing. The surfaces must be adequately drained before contact with beer so little or no residue remains. Allow to air dry.

MILK, CITRUS, AND ICE CREAM PROCESSING PLANTS: Wash and rinse all articles thoroughly with a compatible detergent and rinse with potable water before sanitizing. Applied routinely as a sanitizer (12 ½ ppm to 25 ppm titratable iodine) on walls, conveyors, equipment, and floors, this product will reduce or eliminate odors in the processing area. A contact time of 1 minute is required. Do not rinse after sanitizing. Surfaces must be adequately drained before contact with food so little or no residue remains. Allow to air dry.

Use on filling equipment to reduce or eliminate bacteria associated with condensation on equipment and pipes. Regular use as a sanitizer at 25 ppm will help prevent milk stone formation on equipment. Dilution is 1 ounce per 5 ½ gallons of water.

RECEIVED
OCT 3 2006

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FARM PREMISE DISINFECTANT
DIRECTIONS FOR USE:

DILUTION: 1:256

½ oz. per gallon

1. For use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. 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.
4. Empty all troughs, racks, and other feeding and watering appliances.
- 5/ 3. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
7. 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.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

TURKEY & POULTRY HOUSE DISINFECTANT

Dilution 1 to 256

½ ounce per gallon

DIRECTIONS FOR USE:

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3/ 4. 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 the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

(If container size is 1 gallon or less, the following storage and disposal statements will be used:)

STORAGE AND DISPOSAL

Store in original container in areas inaccessible to children or persons unfamiliar with its proper use. Do not reuse empty container. Discard in trash or recycle.

(If container size is greater than 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

Store in original container in areas inaccessible to children or persons unfamiliar with its proper use. Open dumping is prohibited. 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 or mixture of 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 incineration, or, if allowed by state and local authorities by burning. If burned, stay out of way of smoke.

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

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