

July 28, 2004

Ana Rodriguez-Koster
Lewis & Harrison
122 C Street, NW
Suite 740
Washington, DC 20001

Subject: H&S Chemicals Division c/o Lonza, Inc.
M-2205 Disinfectant/Sanitizer/Cleaner
EPA Registration No. 47371-26
Application Date: January 29, 2004
Receipt Date: January 30, 2004

Dear Ms. Rodriguez-Koster:

This amendment is to add sanitizing claims for effectiveness against additional microorganisms, specifically *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Yersinia enterocolitica*, *Escherichia coli*, *Campylobacter jejuni*, *Shigella sonnei*, and *Salmonella typhi*.

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions given below.

- The revised label claims (as supported by MRID Nos. 461917-01 through 461917-07, in conjunction with previously submitted efficacy data) are acceptable regarding the use of the product, M-2205 Disinfectant/Sanitizer/Cleaner, as a sanitizing rinse on previously cleaned food contact surfaces, against the following microorganisms for a contact time of 1 minute at the conditions listed:

<i>Campylobacter jejuni</i>	at 20±1°C at a 1:704 dilution
<i>Escherichia coli</i> O157:H7	at 20±1°C at a 1:704 dilution
<i>Listeria monocytogenes</i>	at 20±1°C at a 1:704 dilution
<i>Listeria monocytogenes</i>	at 4°C at a 1:350 dilution
<i>Salmonella typhi</i>	at 4°C at a 1:704 dilution
<i>Shigella sonnei</i>	at 20±1°C at a 1:704 dilution
<i>Yersinia enterocolitica</i>	at 20±1°C at a 1:704 dilution

CONCURRENCES

SYMBOL	7510 C						
SURNAME	Mitchell						
DATE	7-28-04						

2. *The Listeria monocytogenes directions for use:*

M-2205 Disinfectant/Sanitizer/Cleaner is effective against Listeria monocytogenes at 4°C (commercial refrigerator temperature) on food contact surfaces in 60 seconds at 1 oz. Per 11 gallons of water.

Should be revised as follows:

M-2205 Disinfectant/Sanitizer/Cleaner is effective as a sanitizing rinse on previously cleaned food contact surfaces against Listeria monocytogenes at 4°C (commercial refrigerator temperature) in 60 seconds at 1 oz. Per 11 gallons of water.

3. *The ATCC has reclassified **Salmonella typhi** (ATCC 6539) as Salmonella choleraesuis subsp. choleraesuis serotype Typhi. You should revise the label to reflect correct nomenclature at both 20±1°C and at 4°C for the Salmonella choleraesuis.*

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,

*Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)*

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER. Harmful if swallowed or inhaled. Avoid breathing vapors. Avoid contact with skin, eyes or clothing. May cause severe eye irritation or eye damage. Causes skin irritation. Wear goggles or face shield and protective gloves (rubber, chemical resistant) when handling. Avoid contamination of food, water or animal feed. 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 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling poison control center or doctor or going for treatment.

(Note to reviewer: If the container size is 5 gallons or larger, the following Environmental Hazards statements will be used :)

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.

M-2205 DISINFECTANT / SANITIZER / CLEANER

Active Ingredient:

Iodine* 1.75%

Other Ingredients: 98.25%

Total..... 100.00%

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

KEEP OUT OF REACH OF CHILDREN

DANGER

EPA Reg. No. 47371-26

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

NET CONTENTS *(insert size of container here)*

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUL 28 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 47371-26

M-2205 Disinfectant / Sanitizer / Cleaner is effective against *Salmonella typhi* at 4°C (commercial refrigerator temperature) on food contact surfaces in 60 seconds at 1 oz. Per 5 ½ gallons of water.

M-2205 Disinfectant / Sanitizer / Cleaner is effective against *Listeria monocytogenes* at 4°C (commercial refrigerator temperature) on food contact surfaces in 60 seconds at 1 oz. Per 11 gallons of water.

DISINFECTANT.....½ 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 1 1:256

SANITIZER:1 oz. per 5 ½ gallons of water

AOAC 200 ppm Available Chlorine Germicidal

Equivalent Concentrate at 20°C

Effective against *Salmonella typhi* and
Staphylococcus aureus 1:704

AOAC 100 ppm Available Chlorine Germicidal

Equivalent Concentrate at 20°C

Effective against *Escherichia coli* O157:H7, *Listeria*
monocytogenes, and *Yersinia enterocolitica* 1:704

AOAC 50 ppm Available Chlorine Germicidal

Equivalent Concentrate at 20°C

Effective against *Escherichia coli*, *Campylobacter*
jejuni and *Shigella sonnei* 1:704

AOAC 50 ppm Available Chlorine Germicidal

Equivalent Concentrate at 4°C

Effective against *Salmonella typhi* 1:704

SANITIZER:1 oz. per 2.7 gallons of water

AOAC 200 ppm Available Chlorine Germicidal

Equivalent Concentrate at 4°C

Effective against *Listeria monocytogenes*..... 1:350

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.

DIRECTIONS FOR USE

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

FOR DISINFECTING: Use on precleaned, hard, nonporous surfaces such as floors, walls, metal surfaces and glazed porcelain surfaces. Remove gross filth and heavy soil deposits. Use 1 oz. of M-2205 Disinfectant / Sanitizer / Cleaner per 2 gallons of water for a minimum contact time of 10 minutes in a single application. Can be applied by a mop, sponge, cloth, coarse trigger sprayer or 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.

Tuberculocidal at a 1:256 dilution in the presence of 400 ppm hard water (calculated as CaCO₃) and moderate amounts of organic soils (5%) for a contact time of 10 minutes at 20°C on hard, nonporous, inanimate surfaces. Follow disinfection directions.

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

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

(or)

This product is not for use on medical device surfaces.

FOR SANITIZING POULTRY DRINKING WATER,

DILUTION: Use 1 oz. of M-2205 Disinfectant / Sanitizer / Cleaner per 11 gallons of water (12½ 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 5½ 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.

FOR SANITIZING: Remove gross food particles and soil by a pre-flush, or pre-scrape, and when necessary, presoak treatment. Use 1 oz. of M-2205 Disinfectant / Sanitizer / Cleaner 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 oz. of M-2205 Disinfectant / Sanitizer / Cleaner in 5½ 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 oz. of M-2205 Disinfectant / Sanitizer / Cleaner per 5½ 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 oz. of M-2205 Disinfectant / Sanitizer / Cleaner 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 oz. of M-2205 Disinfectant / Sanitizer / Cleaner 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 oz. of M-2205 Disinfectant / Sanitizer / Cleaner 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 (12½ 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.

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. 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 DIRECTIONS FOR USE:

DILUTION: 1:256 ½ OZ. PER GALLON

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. 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.

STORAGE AND DISPOSAL

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

Pesticide Storage:

Keep product under locked storage, inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

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, 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 incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

(FIBER DRUMS WITH LINERS): Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then, dispose of liner in a sanitary landfill or by incineration, if allowed by state and local authorities. If drum is contaminated and cannot be reused, dispose of in the same manner.

(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.