

14 MAR 1991

H&S Chemicals Division
970 East Tipton Street
Huntington, IN 46750

Attention: Sally Hayes
Manager, Regulatory Affairs

BEST AVAILABLE COPY

Gentlemen:

Subject: M-2205 Farm Disinfectant/Sanitizer
EPA Registration No. 47371-93
Your Submission Dated April 10, 1991

This is in response to your resubmission regarding your request to amend the registration of the subject product to include a tuberculocidal claim and an additional virucidal claim.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable provided that you:

1. Make the following labeling revisions before releasing the product for shipment bearing the amended labeling:
 - a. In the directions for use of this product entitled "Sanitizing bottles and cans," change "8-12 ppm" in line 2 to read "25 ppm."
 - b. Also, in lines 2 & 5 of the directions referred to above, change "11-12 gallons" to read "5 1/2 gallons." Note that in rereviewing these directions in this section, it was determined that the recommended dilution rate for sanitizing should be the same as in the other recommended use areas.
2. Submit the final printed labeling before releasing the product for shipment bearing the amended labeling.

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CONCURRENCES

SYMBOL							
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Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,



Ruth G. Douglas
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

BEST AVAILABLE COPY

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(FRONT PANEL)

M-2205 FARM DISINFECTANT/SANITIZER

ACTIVE INGREDIENT

Iodine* 1.75%
Inert Ingredients: 98.25%

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

KEEP OUT OF REACH OF CHILDREN

DANGER

(See right panel for additional precautionary and practical treatment statements.)

EPA Registration #47371-93 EPA Establishment #47371-IN-01

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H&S Chemicals Division • 970 East Tipton • Huntington, IN 46750

ACCEPTED
with COMMENTS
in EPA Letter Dated

14 JUN 1991
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
47371-93

14 JUN 1991

(LEFT PANEL M-2205 FARM DISINFECTANT/SANITIZER)

DIRECTIONS FOR USE

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

47371-93

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

For use in poultry and turkey farms, life science animal cages, veterinary clinics, hospitals, nursing homes, medical and dental offices, dairy use, federally inspected meat and poultry plants, and food processing equipment (See bulletin for Poultry House & Farm Premise use directions.).

DISINFECTANT ½ ounce 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 ounce per 5½ gallons of water

AOAC AVAILABLE CHLORINE GERMICIDAL EQUIVALENT CONCENTRATE:

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

FOR DISINFECTING: For use on precleaned hard non-porous surfaces such as floors, walls, metal surfaces, and porcelain surfaces. Remove gross filth and heavy soil deposits. Preclean all surfaces prior to disinfecting. Use 1 ounce per 2 gallons of water for a minimum contact time of 10 minutes in a single application. Can be applied by spraying or soaking. The recommended use solution is prepared fresh for each use then discarded.

Tuberculocidal at a 1:256 dilution in the presence of moderate amounts of organic soils (5%) and synthetic hard water (calculated as CaCO_3) for a contact time of 10 minutes at 20°C on hard non-porous, inanimate surfaces. Remove gross filth and heavy soil deposits, then thoroughly wet surfaces. Can be applied with mop, sponge, or cloth as well as soaking or spraying. The recommended use solution is used once and discarded.

FOR SANITIZING POULTRY DRINKING WATER, DILUTION: 1 ounce per 11 gallons of water. 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. When solution becomes visibly dirty, discard and provide fresh solution.

FOR SANITIZING: Remove gross food particles and soil by a preflush, or prescrape and; when necessary, presoak treatment. Use 1 ounce per 5½ 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. A potable water rinse is not required following use of this compound on previously cleaned hard surfaces. However, the 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, the requirement that fresh sanitizing solution must be prepared at least daily, or more often if the solution becomes diluted or soiled.

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(LEFT PANE CONTINUED M-2205 FARM DISINFECTANT/SANITIZER)

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. A potable water rinse is not required following use of this compound on previously cleaned hard surfaces. However the surfaces must be adequately drained before contact with food so that little or no residue remains.

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, then apply a solution of 1 ounce in 5 1/2 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 and immerse in a solution (1 ounce per 5 1/2 gallons) 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: Thoroughly rinse bottling and premix dispensers with water. Drain thoroughly and fill equipment with 25 ppm sanitizing solution. Just before resuming operation, drain the equipment thoroughly. Do not rinse. System should not be rinsed with potable water. 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. System should not be rinsed with potable water. Allow to air dry. Dilution is 1 ounce per 5 1/2 gallons of water.

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SANITIZING BOTTLES AND CANS: Proportion into the final rinse of the container washer or rinses in concentration of 8-12 ppm titratable iodine. Use one ounce per ~~11-12~~ 11-12 gallons of water for a minimum contact time of one minute. A potable water rinse is not required following use of this compound on previously cleaned hard surfaces. However, the surfaces must be adequately drained before contact with food so that little or no residue remains. Allow to air dry. Dilution is 1 ounce per ~~11-12~~ 11-12 gallons of water. 5 1/2

SANITIZING STORAGE TANKS: After cleaning, use a 25 ppm solution for sanitizing beer fermentation and holding tanks. Use solution can be applied by spraying or can be used in conjunction with automated clean-in-place systems. A contact time of 1 minute is required. No water rinse is required after sanitizing. However, surfaces must be adequately drained before contact with beer so little or no residue remains. Allow to air dry. Dilution is 1 ounce per 5 1/2 gallons of water. 5 1/2

MILK, CITRUS, AND ICE CREAM PROCESSING PLANTS: Applied routinely as a sanitizing spray (12 1/2 ppm to 25 ppm titratable iodine) on walls, conveyors, equipment, and floors will reduce or eliminate odors in the processing area. A contact time of 1 minute is required. Use on filling equipment to reduce or eliminate bacteria associated with condensation on equipment and pipes. Regular use as a sanitizer at 25 ppm helps prevent milk stone formation on equipment. However, surfaces must be adequately drained before contact with food so little or no residue remains. Allow to air dry. Dilution is 1 ounce per 5 1/2 gallons of water.

ACCEPTED
with COMMENTS
in EPA Letter dated:

14 JUN 1991

Under the Federal Insecticide,
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(RIGHT PANEL M-2205 FARM DISINFECTANT/SANITIZER)

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 rubber gloves when handling. Avoid contamination of food, water, or animal feed. Wash contaminated clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician immediately. If swallowed, drink promptly a large quantity of water. Call a physician immediately.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

STORAGE AND DISPOSAL

This product must be kept under locked storage sufficient to make it inaccessible to children or persons unfamiliar with its proper use.

PROHIBITIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or residue 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; incinerate; or, if allowed by state and local authorities, by burning. 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.

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