

70799-13

9/10/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

SEP 10 2013

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Eric Miklos, Regulatory Affairs Manager
State Industrial Products
3100 Hamilton Ave.
Cleveland, OH 44114

Subject: **State Chlorine Sanitizer**
EPA Registration No. 70799-13
Application Date: 1/22/13
Receipt Date: 1/31/2013

Dear Mr. Mitklos:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 5 as amended, is acceptable.

Proposed Amendment:

- Include sporicidal claims against *Clostridium Difficile*
- Amend label to match the dilution to support the submitted efficacy data

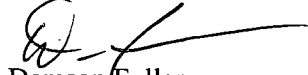
General Comments

A stamped label is enclosed for your records. The efficacy review is also enclosed. A stamped label is enclosed for your records. Please submit a final printed label before selling or distributing the product bearing the revised labeling. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you have any questions concerning this letter, you may contact me by telephone at Nathan Mottl at (703) 305-0208 or by email at mottl.nathan@epa.gov during the hours of 7:30 am to 4:30 pm EST.

When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Demson Fuller
Acting Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

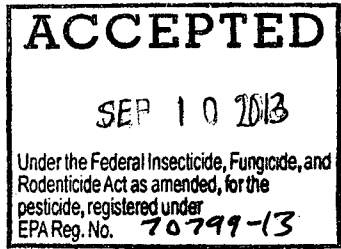
**Enclosed: Stamped Label
Efficacy review**

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STATE CHLORINE SANITIZER

COMMERCIAL
INSTITUTIONAL USE

DISINFECTS • SANITIZES



This product may be used on hard non-porous surfaces in commercial, institutional and hospital premises eating establishments, and food processing plants.

ACTIVE INGREDIENT:

Sodium Hypochlorite..... 6.0%

OTHER INGREDIENTS:..... 94.0%

TOTAL..... 100.0%

Yields 5.7% available chlorine.

Contains no phosphorus.

KEEP OUT OF REACH OF CHILDREN DANGER

EPA Registration Number: 70799-13

EPA Establishment Number: 70799-OH-2

State Industrial Products
5915 Landerbrook Drive
Mayfield Heights, Ohio 44124
1.877.747.6986

NET CONTENTS: *[Insert Sizes]*

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

One Tbsp. (½ oz.) of this bleach in 5 quarts of water is equivalent to approximately 200 parts per million (ppm) available chlorine. Use a chlorine test kit to determine exact available chlorine concentration and adjust as necessary to obtain specified ppm.

SANITIZING FOOD CONTACT SURFACES: Before using this product, remove or carefully protect food. Remove gross food particles from surface. Prewash surface with a good detergent and rinse thoroughly with potable water. Mix approximately 1 tablespoon of bleach per 5 quarts of water to prepare a 200 ppm available chlorine solution. Cover surface with bleach solution for at least 2 minutes. Air dry.

DISINFECTING KITCHEN, DISHES, AND SINKS: Prepare sanitizing solution immediately prior to use.

1. 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 potable water.
4. Sanitize articles using a solution of 5 ½ ounce of this product diluted into 1 gallon of water. Articles that can be immersed in solution must remain in solution for 10 minutes. Articles too large for immersing must be thoroughly wetted by rinsing, spraying or swabbing.
5. Do not rinse. Allow sanitized surfaces to adequately drain before contact with food.

SANITIZING NONPOROUS FOOD CONTACT SURFACES: Prepare a sanitizing solution by thoroughly mixing 2 Tbsp. (1 oz.) of this product with 2 ½ gallons of water to provide approximately 200 ppm available chlorine by weight. Clean all surfaces in the normal manner. Prior to use, rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. Do not rinse equipment with water after treatment and do not soak equipment overnight.

PROPORTIONS FOR DILUTIONS OF THIS PRODUCT

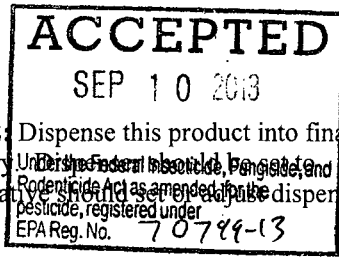
100 ppm; 0.5 oz. (1 Tbsp) in 2 ½ gallons of water

200 ppm; 1oz. (2 Tbsp) in 2 ½ gallons of water

600 ppm; 3oz. (6 Tbsp) in 2 ½ gallons of water

(Use a chlorine test kit to determine exact available chlorine concentration and adjust dosage as necessary.)

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WAREWASHING

FOR SANITIZING TABLEWARE IN LOW TEMPERATURE DISHWASHING MACHINE: Dispense this product into final rinse water at 100 ppm available chlorine. Do not allow concentration to fall below 50 ppm. Air dry. Deliver sanitizing solution to give 100 ppm of available chlorine. Only a qualified service representative should service the dispenser on the machine.

RESTAURANTS, TAVERNS, SODA FOUNTAINS, DAIRIES DIRECTIONS FOR SANITIZING EATING AND DRINKING UTENSILS:

Prepare sanitizing solution immediately prior to use. 1. Scrape and pre-wash utensils and glass whenever possible. 2. Wash with good detergent or compatible cleaner. 3. Rinse with clean water. 4. Sanitize in solution of 1 oz to 2 ½ gallons of water (200 ppm). 5. Immerse utensils at least 2 minutes or for contact time specified by governing sanitary code. 6. Do not reuse sanitizing solution.

TABLE OF PROPORTIONS AVAILABLE CHLORINE

600 ppm - 12 oz. in 10 gal. water 200 ppm - 4 oz. in 10 gal. water 100 ppm-2 oz. in 10 gal water

SANITIZATION OF NON-POROUS FOOD CONTACT SURFACES

RINSE METHOD - A solution of 100 ppm available chlorine may be used in the sanitizing solution if a chlorine test kit is available. Solutions containing an initial concentration of 100 ppm available chlorine must be tested and adjusted periodically to insure that the available chlorine does not drop below 50 ppm. Prepare a 100 ppm sanitizing solution by thoroughly mixing 2 oz. of this product with 10 gallons of water. If no test kit is available, prepare a sanitizing solution by thoroughly mixing 4 oz. of this product with 10 gallons of water to provide approximately 200 ppm available chlorine by weight. Clean equipment surfaces in the normal manner. Prior to use, rinse all surfaces thoroughly with the sanitizing solution, maintaining contact with the sanitizer for at least 2 minutes. If solution contains less than 50 ppm available chlorine, as determined by a suitable test kit, either discard the solution or add sufficient product to reestablish a 200 ppm residual. Do not rinse equipment with water after treatment and do not soak equipment overnight. Sanitizers used in automated systems may be used for general cleaning but may not be re-used for sanitizing purposes.

IMMERSION METHOD - A solution of 100 ppm available chlorine may be used in the sanitizing solution if a chlorine test kit is available. Solutions containing an initial concentration of 100 ppm available chlorine must be tested and adjusted periodically to ensure that the available chlorine does not drop below 50 ppm. Prepare a 100 ppm sanitizing solution by thoroughly mixing 2 oz. of this product with 10 gallons of water. If no test kit is available, prepare a sanitizing solution by thoroughly mixing 4 oz. of this product with 10 gallons of water to provide approximately 200 ppm available chlorine by weight. Clean equipment in the normal manner. Prior to use, immerse equipment in the sanitizing solution for at least 2 minutes and allow the sanitizer to drain. If solution contains less than 50 ppm available chlorine, as determined by a suitable test kit, either discard the solution or add sufficient product to reestablish a 200 ppm residual. Do not rinse equipment with water after treatment.

Sanitizers used in automated systems may be used for general cleaning but may not be re-used for sanitizing purposes.

CLEAN-IN-PLACE METHOD - Thoroughly clean equipment after use. Prepare a volume of a 200 ppm available chlorine sanitizing solution equal to 110% of volume capacity of the equipment by mixing the product in a ratio of 4 oz. product with 10 gallons of water. Pump solution through the system until full flow is obtained at all extremities, the system is completely filled with the sanitizer and all air is removed from the system. Close drain valves and hold under pressure for at least 10 minutes to ensure contact with all internal surfaces. Remove some cleaning solution from drain valve and test with a chlorine test kit. Repeat entire cleaning/sanitizing process if effluent contains less than 50 ppm available chlorine.

BACTERICIDAL/FUNGICIDAL ACTIVITY

This product, when used as directed, is effective against the following bacteria and fungi: *Staphylococcus aureus* (ATCC 6538), *Streptococcus pyogenes* (ATCC 19615), *Salmonella enteric* (ATCC 10708), *Pseudomonas aeruginosa* (15442), *Shigella dysenteriae* (ATCC 9361), *Escherichia coli* (ATCC 11229). Effective against *Trichophyton mentagrophytes* (ATCC 9533) using immersion method directions above and immerse equipment in sanitizing solution for at least 5 minutes. Controls *Aspergillus niger* (ATCC 6275) on pre-cleaned, hard, non-porous surfaces. Kills *Clostridium difficile* spores (*C. diff*) [#] (ATCC 43599) On Hard Non-Porous [Environmental] Surfaces.

DIRECTIONS FOR USE: Hard Non-porous Surfaces: To disinfect hard non-porous surfaces, (first) clean surface by removing gross filth (loose dirt, debris, food materials). Prepare a 2700 ppm available chlorine solution by diluting 1 part bleach to 22 parts water. Thoroughly wet surface with the solution and allow to remain on the surface for 5 minutes. Rinse with clean water and dry.

DIRECTIONS FOR USE: Mildewstat: To control mold and mildew (*Aspergillus niger* (ATCC 6275)) on pre-cleaned, hard, non-porous surfaces. Prepare a 2700 ppm available chlorine solution by diluting 1 part bleach to 22 parts water. Thoroughly wet surface to be treated making sure to wet completely and maintaining contact with sanitizer for at least 5 minutes. Let air dry. Repeat application at weekly intervals or when mildew growth appears.

Special Label Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with

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SEP 10 2008
Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
Pesticide, registered under
EPA Reg. No. 70799-13

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clean cloth, mop, and/pr sponge saturated with product intended for disinfection. Cleaning should include vigorous wiping and/or scrubbing, until visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms should be cleaned in an appropriate manner, with restrooms and other 'dirty' areas cleaned last. Do not reuse soiled cleaning materials. **Infectious Materials Disposal:** Cleaning materials used that may contain feces/wastes should be disposed in accordance with local regulations for infectious materials disposal.

Killing *Clostridium difficile* spore: Add 1 part bleach to 5 parts water to achieve a 1:6 dilution (~10,000 ppm available chlorine) before use. Clean hard, nonporous surfaces by removing gross filth, loose debris, blood/bodily fluids. Apply 1:5 solution and let stand for 10 minutes. Rinse and air dry. Prepare a fresh solution daily. Avoid contact with surfaces that may be damaged by bleach. Do not use on non-stainless steel, aluminum, silver, or chipped enamel.

COOLING TOWER/EVAPORATIVE CONDENSER WATER

SLUG FEED METHOD: Initial Dose: When system is noticeably fouled, apply 107 to 213 oz. of this product per 10,000 gallons of water in the system to obtain from 5 to 10 ppm available chlorine. Repeat until control is achieved. **Subsequent Dose:** When microbial control is evident, add 21 oz. of this product per 10,000 gallons of water in the system daily, or as needed to maintain control and keep the chlorine residual at 1 ppm. Badly fouled systems must be cleaned before treatment is begun.

INTERMITTENT FEED METHOD: Initial Dose: When system is noticeably fouled, apply 107 to 213 oz. of this product per 10,000 gallons of water in the system to obtain 5 to 10 ppm available chlorine. Apply half (or 1/3, 1/4, or 1/5) of this initial dose when half (or 1/3, 1/4, or 1/5) of the water in the system has been lost by blowdown. **Subsequent Dose:** When microbial control is evident, add 21 oz. of this product per 10,000 gallons of water in the system to obtain a 1 ppm residual. Apply half (or 1/3, 1/4, or 1/5) of this initial dose when half (or 1/3, 1/4, or 1/5) of the water in the system has been lost by blowdown. Badly fouled systems must be cleaned before treatment is begun.

CONTINUOUS FEED METHOD: Initial Dose: When system is noticeably fouled, apply 107 to 213 oz. of this product per 10,000 gallons of water in the system to obtain 5 to 10 ppm available chlorine. **Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 2 oz. of this product per 1,000 gallons of water lost by blowdown to maintain a 1 ppm residual. Badly fouled systems must be cleaned before treatment is begun.

LAUNDRY SANITIZERS

Commercial Laundry Sanitizers: Wet fabrics or clothes should be spun dry prior to sanitization. Thoroughly mix 4 oz. of this product with 10 gallons of water to yield 200 ppm available chlorine. Promptly after mixing the sanitizer, add the solution into the prewash prior to washing fabrics/clothes in the regular wash cycle with a good detergent. Test the level of available chlorine, if solution has been allowed to stand. Add more of this product if the available chlorine level has dropped below 200 ppm.

FIRST AID

Call poison control center or doctor immediately for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
You may also contact the International Poison Center at 1-888-740-8712.
IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.
IF SWALLOWED: 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.

SDS available at www.stateindustrial.com or 1-800-782-2436

PRECAUTIONARY STATEMENTS

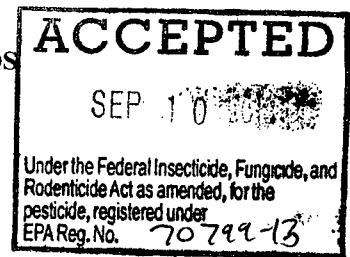
Hazards to Humans and Domestic Animals

DANGER: Corrosive, Causes skin burns and substantial but temporary eye injury. Do not get in eyes, on skin, or on clothing. Wear safety glasses and rubber gloves when handling this product. Harmful if inhaled. Avoid breathing vapors. Wash thoroughly with soap and water before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

Physical and Chemical Hazards

Strong oxidizer. Flush drains before and after use. Do not use or mix with other household chemicals, such as toilet bowl cleaners, rust removers, acid or ammonia containing products. To do so will release hazardous gases. Prolonged contact with metal may cause pitting or discoloration.

DO NOT MIX WITH AMMONIA - DO NOT MIX WITH ACIDS



STORAGE AND DISPOSAL

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

Pesticide Storage: Keep container closed when not in use. All pesticides must be kept out of the reach of children and stored away from food.

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.

[For rigid Household/Residential Products][For rigid non-refillable container less than 5 gallons] Container Handling: Nonrefillable rigid container. Do not re-use or refill this container. Triple rinse (or equivalent) promptly after emptying. Offer for recycling, if available, or throw in trash.

[For Commercial/Industrial/Institutional Products][For rigid non-refillable container less than 5 gallons] Container Handling: Non-refillable rigid container. Do not re-use or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tanks and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank and store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. 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 of smoke.

[For Commercial/Industrial/Institutional Products][For rigid nonrefillable container greater than 5 gallons] Container Handling: Nonrefillable rigid container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container % full with water. Replace and tighten closures. Tip containers on its end and tip it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for the later use or disposal. Repeat this procedure two more times. 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 of smoke.