

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 6, 2016

Ms. Tamra Barrick Regulatory Specialist Preserve International 944 Nandino Boulevard Lexington, KY 40511

Subject: Notification per PRN 98-10 – Minor Label Changes to Reflect Acquisition

Product Name: Mycocide

EPA Registration Number: 66171-8 Application Date: October 26, 2016

Decision Number: 523167

Dear Ms. Barrick:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Page 2 of 2 EPA Reg. No. 66171-8 Decision No. 523167

If you have any questions, you may contact Killian Swift at 703-308-6346 or via email atSwift.Killian@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Mycocide GERMICIDAL DETERGENT SANITIZER For Industrial Use Only

A low-foaming sanitizer for food, meat and beverage industries

*Active	Ingredient	:
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 Iodine*
 3.5%

 Other Ingredients:
 96.5%

 Total:
 100.00%

*from polyoxyethylene-polyoxypropylene block polymer-iodine complex

*Provides 3.5% titratable iodine (w/w) or 4.2% titratable iodine (v/v). Specific Gravity1.2.

EPA Reg. No. 66171-8

EPA Est. No. 66171-TN-001 EPA Est. No. 66171-CA-001 EPA Est. No. 61282-WI-001 EPA Est. No. 47000-IA-001

(First letter of batch number indicates establishment)

KEEP OUT OF REACH OF CHILDREN DANGER

See left (back) (side) (right) panel (of label) (below) for additional precautionary statements

Net Contents:

1 gallon (3.8L) 15 gallons (56.8L) 55 gallons (208L)

Code: TBD

Label No(s): TBD

NOTIFICATION

66171-8

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

12/06/2016

Manufactured By:

Preserve International 944 Nandino Blvd.
Lexington, KY 40511

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes eye damage and skin damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic animals. Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water 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.

PHYSICAL AND CHEMICAL HAZARDS: Do not use, pour, spill or store near heat or open flame.

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. Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. 		
If on Skin or Clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center, or doctor, or 1-800-498-5743 immediately for treatment advice. 		
If Inhaled:	 Move person to fresh air. If not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center, or doctor, or 1-800-498-5743 for treatment advice. 		
If Swallowed:	 Call a poison control center, or doctor, or 1-800-498-5743 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. 		
HOT LINE NUMBER			

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

DIRECTIONS FOR USE

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

USE SOLUTION CHART

Titratable Iodine	Mycocide	Water
50 ppm solution	1 oz.	6 1/2 gals.
25 ppm solution	1 oz.	13 gals.
12 1/2 ppm solution	1 oz.	26 gals.
10 ppm solution	1 oz.	32 gals.
8 ppm solution	1 oz.	40 gals.

Refer to use solution chart when preparing dilutions recommended in the following directions.

Always prepare fresh sanitizing solutions and use them the same day prepared. All sanitizing solutions should contact surfaces at least two minutes. When circulations sanitizer solutions thorough CIP systems, allow at least 5 minutes contact.

FOOD AND BEVERAGE SANITIZATION PROCEDURES

Prior to sanitizing, remove gross filth by either flushing, scraping or soaking the desired area to be sanitized. Wash surfaces or objects with detergent or cleaner and rinse with potable water.

Soft Drink Plants: Thoroughly rinse bottling and pre-mix dispensers with water. Drain thoroughly and fill equipment with 25 ppm solution (refer to use solution chart). Just before resuming operation flush 25 ppm solution from equipment with potable water. When changing over between soft drink flavors, rinse system well with water, flush with 25 ppm solution. Drain thoroughly before use.

Sanitizing Bottles and Cans: Proportion Mycocide into the final rinse of the container washer or rinses in concentrations of 8-12 ppm titratable iodine (see use solution chart).

Sanitizing Storage Tanks: After cleaning, use a 25 ppm solution for sanitizing beer fermentation and holding tanks. Use solution can be applied by using a coarse spray or can be used in conjunction with automated clean-in-place systems. No water rinse is required after sanitizing. Drain thoroughly before use.

Equipment in Poultry, Meat, Rabbit, Egg Processing Plants, Frozen and Fresh Pack Processing Plant: To clean equipment, scrub surfaces with a mop, brush, sponge or cloth using 50 ppm solution. Rinse with potable water. For sanitizing previously cleaned surfaces, apply 25 ppm solution by using a coarse spray, flushing, or with a clean sponge. Thoroughly wet surfaces and allow to thoroughly drain. No final water rinse is required.

Sanitizing Poultry Drinking Water: For sanitizing poultry drinking water, use one ounce Mycocide for every 52 gallons of water providing 6 ppm titratable iodine. Continuously proportioned in water line. Drain thoroughly before use.

Mycocide EPA Reg. No. 66171-8 Page 4 of 7

Milk, Citrus and Ice Cream Processing Plants: Applied routinely as a sanitizing coarse spray (12.5 ppm to 25 ppm titratable iodine) on walls, conveyors, equipment and floors. Mycocide will reduce or eliminate odors in the processing area. 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. Drain thoroughly before use.

Retort Cooling Water: Mycocide helps reduce the growth of microorganisms in retort cooling water. Mycocide should be added to the retort cooling water in sufficient quantity to maintain 0.1 to 0.5 ppm titratable iodine at the discharge side. To reach this level of iodine, an initial concentration of 5 ppm titratable iodine is recommended (1 ounce of Mycocide to 55 gallons of water.) The amount of Mycocide required will depend on the organic load and the alkalinity of the water. A suitable iodine test kit, capable of measuring titratable iodine in the range of 0.1 to 0.5 ppm, should be used to check iodine levels.

FOR USE IN DARIES

Back-Flush for Teat Cups on Dairy Farms: To clean/sanitize milking machine test cups between cows, rinse with clean water, then inject 1 ounce Mycocide per 26 gallons of water (12.5 ppm) or 1 ounce Mycocide per 13 gallons of water (25 ppm), flush, and drain from the unit. Do not re-use solution.

Milking claw systems: For use through claws between milking each cow. Helps reduce micro-organisms on liners which may cause mastitis.

- 1. Pre-rinse thoroughly with potable water or a thoroughly mixed solution containing 1 ounce of Mycocide per 13 gallons of water. This solution provides 25 ppm titratable iodine.
- 2. Flush system with a thoroughly mixed solution containing 1 ounce of Mycocide per 13 gallons of water. Allow at least one minute contact time.
- 3. Thoroughly drain system.

Wash Down Hoses: For general cleaning in the milking parlor use a thoroughly mixed solution containing 1 ounce of Mycocide per 13 gallons of water. Thoroughly rinse down all surfaces

For Use as an Udderwash: To clean cows' teats prior to milking, use a well-mixed solution containing 1 ounce of Mycocide per 13 gallons of water. Wash teats and flanks thoroughly. and then dry with a clean. single service paper towel.

IMPORTANT: Follow State and local Health Department requirements for sanitizing milking equipment. Do not mix Mycocide with hot water. Use cool or tepid water only.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. 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 or Environmental Control Agency or the hazardous waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll 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. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

(For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank 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 or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

GENERAL: Consult Federal, State or local disposal authorities for approved alternative procedures.

DOT Shipping Name: Disinfectants, Liquid, Corrosive, n.o.s. (Phosphoric acid), 8, UN1903, PG II

NFPA Hazard Classification:

 $\begin{aligned} & \text{Health} - 2 \\ & \text{Fire} - 0 \\ & \text{Reactivity} - 0 \\ & \text{Specific} - \text{Acid} \end{aligned}$

Optional Warranty Statements:

DISCLAIMER: To the extent permitted by applicable law, seller makes no representation or warranty, either express or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.

LIMITED WARRANTY

To the extent permitted by applicable law, Preserve International and Neogen Corporation make no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent permitted by applicable law, Preserve International and Neogen Corporation shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

OR

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

To the extent permitted by applicable law Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent permitted by applicable law, in no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF THE MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

For non-emergency (e.g., current product information),

Call: 1-800-621-8829

Mycocide EPA Reg. No. 66171-8 Page 7 of 7

Optional Subsidiary Statement:

Preserve International is a wholly-owned subsidiary of Neogen Corporation.

Optional Logo(s):



«Preserve International logo»



«Neogen Corporation logo»



«Neogen Flask icon»







«PPE icon(s)» (examples)