



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

6836-399

Date of Issuance:

7/23/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Sodium Omadine® 10% Aqueous
Solution - Lonza Industrial Bactericide
and Fungicide

Name and Address of Registrant (include ZIP Code):

Stephanie Stephens
Lonza, Inc.
412 Mount Kemble Avenue
Suite 200S
Morristown, NJ 07960

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Date:

7/23/19

2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Sodium, 2-pyridinethiol-1-oxide GDCI-088004-1663

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 6836-399.”
4. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/29/2019

If you have any questions, please contact Jake McFarley by phone at (703) 347-0123, or via email at McFarley.Jake@epa.gov.

Enclosure: Product Master Label

SODIUM OMADINE® 10% AQUEOUS SOLUTION - LONZA INDUSTRIAL BACTERICIDE AND FUNGICIDE

ALTERNATE BRAND NAMES:

SODIUM OMADINE 10% - LONZA FUNGICIDE

SODIUM OMADINE 10% AQUEOUS SOLUTION – LONZA INDUSTRIAL FUNGICIDE & BACTERICIDE

ACTIVE INGREDIENT:

Sodium, 2-pyridinethiol-1-oxide 10%

Inert Ingredients 90%

Total 100%

EPA Reg. No. 6836-GOO

EPA Est. No. 1258-NY-3

KEEP OUT OF REACH OF CHILDREN

WARNING

SEE FIRST AID & ADDITIONAL PRECAUTIONARY STATEMENTS ON SIDE PANEL

MANUFACTURED FOR:

Lonza, Inc.

412 Mount Kemble Avenue, Suite 200S

Morristown, NJ 07960

Made in the USA.

OMADINE® is a registered trademark of Lonza, Inc.

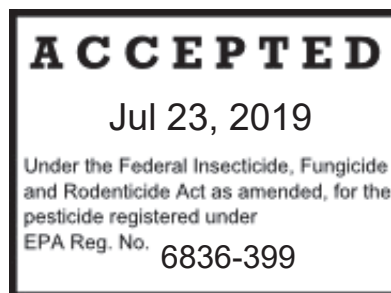
Net Weight 25 Lbs.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS. May be fatal if absorbed through the skin. Causes skin irritation and moderate eye irritation. Harmful if swallowed or inhaled. Do not get in eyes, on skin, or on clothing.

PERSONAL PROTECTIVE EQUIPMENT (PPE): Applicators and other handlers must wear: goggles or face shield, long sleeved shirt and long pants, socks and shoes, chemical-resistant gloves (such as rubber or waterproof gloves).

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Users should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing.



FIRST AID:

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 for treatment advice.

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 for treatment advice.

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.

If Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for further 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.

In case of emergency, for additional information call 1-800-654-6911.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, ponds, streams, 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.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Do not store above 130 degrees F. (55 deg. C.). Keep container tightly closed when not in use. Do not store with strong oxidizing agents.

PESTICIDE DISPOSAL Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container promptly after emptying. 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.

[For containers >5 gallons] Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 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. Then offer for recycling or reconditioning. If not available, puncture and dispose of in a sanitary landfill.

[For containers ≤5 gallons] Triple rinse as follows: Empty 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. Then offer for recycling or reconditioning. If not available, puncture and dispose of in a sanitary landfill.

[For Totes/IBCs] Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and reclose the container. Agitate vigorously, and dispose of rinsate consistent with pesticide disposal instructions. Repeat two more times. Then offer for recycling if available or puncture and dispose in sanitary landfill or by other procedures approved by state and local authorities. Follow pesticide disposal instructions for rinsate. If not triple rinsed, these containers are acute hazardous wastes and must be disposed in accordance with local, state, and federal regulations.

[For Bulk Shipments and Transport Vehicles such as Portable Tanks, Tanker Trucks, Tank Trailers and Railcars] Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to point of sale or offer for recycling if available or reconditioning if appropriate.

DIRECTIONS FOR USE: It is a violation of federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons. Do not use for applications involving direct or indirect food / drinking water contact.

IN AQUEOUS BASED FLUIDS SUCH AS METALWORKING, CUTTING, COOLING AND LUBRICATING FLUIDS: To inhibit bacterial and fungal growth add an initial dose of up to 5000 ppm of this product (5 lbs. of this product to 1,000 lbs. of solution) to the solution by pouring from the container and subsequent maintenance doses of up to 5000 ppm (5 lbs. of the product per 1,000 lbs. of solution) every 7- 10 days or as needed. This product can be used at fluid to water ratios of 1: 10 to 1: 100. This product may be added to the fluid at the time it is prepared (diluted) or to the reservoir (sump) containing the fluid after it is put into use. If it is added to the reservoir, the fluid should be circulated after addition to ensure mixing. Contaminated fluid systems should be cleaned prior to the initial addition of this product. Drain the system, clean with a cleaner designed for this purpose, rinse with water and refill with fresh fluid containing this product (up to 5000 ppm). Frequent checks (at least once a week) of the bacterial and fungal population in the system should be made using standard microbiological plate count procedures or any of the commercial "dip- stick" type devices. When the bacterial count reaches 10^7 and/ or the fungal count reaches 10^3 organisms per ml, add additional product according to the above directions. If this does not reduce the bacterial and/ or fungal count below the above value in 12- 24 hours, the fluid should be discarded and replaced after cleaning the system. Add this product to the fresh fluid according to the above directions. When adding fresh, diluted fluid to compensate for dragout or other losses, add this product to make- up fluid according to the above directions.

TO INHIBIT THE GROWTH OF BACTERIA AND FUNGI IN METALWORKING, CUTTING, COOLING AND LUBRICATING FLUID CONCENTRATES: Add an amount that will give up to a 5000 ppm solution. The amount required in the concentrate will depend on the end use dilution. For example: If the desired level of this product is 1000 ppm and the end use dilution of the fluid is 5%, then a 2.0% concentration of this product is required in the concentrate ($1000 \text{ ppm} / 0.05 = 20,000 \text{ ppm}$ or 2.0%).

FOR THE IN-CAN PRESERVATION OF LATEX EMULSIONS USED IN ADHESIVES, CAULKS, PATCHING COMPOUNDS, SEALANTS, PASTES AND GROUTS: To inhibit bacterial growth in latex emulsions for a period of up to 1 year, a dosage of up to 4000 ppm of this product (4 lb. of this product per 1,000 lbs. of emulsion) is recommended. Product may be added at any time during the formulation procedure by pouring from the container.

IN AQUEOUS SYNTHETIC FIBER LUBRICANTS (SPIN FINISHES): To inhibit the growth of bacteria and the formation of bacterial slime in synthetic fiber lubricants (spin finishes) for periods of 2- 4 weeks during use, add 5000 ppm (5 lbs. per 1,000 lbs. of lubricant) of this product to the diluted lubricant. This product may be used in lubricant solutions containing 5- 10% lubricant concentrate (water to lubricant ratios of 20- 1 to 10- 1). This product should be added by pouring from the container to the diluted lubricant in the dilution tank.

IN AQUEOUS BASED INKS: To inhibit the growth of bacteria and fungi in inks such as aqueous based inks, printing solutions, pigment slurries or press cake, add up to 4000 ppm of this product. While the inks are in use, a concentration of 4% w/ w of this product is necessary. The amount of this product to be added at the time of manufacture of the ink to obtain the above concentrations, at the time of use, will vary with the shelf- life of the ink. The table below shows the relationship.

Shelf- Life Ink (months)	%Sodium Omadine 10%
36	4.00
24	2.60
18	1.9
12	1.25
8	1.00

To inhibit the growth of bacteria in neutral or slightly acidic aqueous based jet- printer inks for periods of up to 4 weeks while the inks are in use, add 3% w/ w of this product to the ink at the time of manufacture. To avoid decomposition of this product during shelf- life of the ink, airtight packaging must be used. In all cases, this product may be added to the ink at any point in the manufacturing process by pouring from the container.

FOR THE DRY FILM PRESERVATION OF NATURAL AND SYNTHETIC ADHESIVES, LATEXES, URETHANE FOAMS, CAULKS, PATCHING COMPOUNDS, SEALANTS, ARCHITECTURAL PAINTS, INDUSTRIAL PAINTS AND COATINGS (Including wood coatings), PASTES AND GROUTS: Addition of up to 20000 ppm (20 lbs. of this product per 1000 lbs. of formulation) of this product can inhibit microbial growth (bacteria and fungi) in the dry film of these products. This product can be added at any time during the formulation procedure. For example, sheet vinyl adhesives used in the installation of vinyl flooring can be preserved by the addition of 8400 ppm of this product (8.4 lbs. per 1000 lbs. of adhesive).

FOR THE IN- CAN PRESERVATION OF LAUNDRY RINSE ADDITIVES, LAUNDRY DETERGENTS, CARPET CLEANERS, SURFACT CLEANERS, FLOOR CLEANERS: To inhibit the growth of bacteria and fungi in laundry rinse additives for periods of up to one year, add 0.64% w/w (6400 ppm or 6.4 lbs. of this product per 1000 lbs. of formulation). This product can be added at any time during the formulation procedure.

FOR THE IN- CAN PRESERVATION OF WATER BASED CHEMICAL OR MINERAL ADD MIXTURES THAT ARE USED IN CONCRETE: Addition of up to 4000 ppm of this product can inhibit microbial growth (bacteria and fungi) in add mixtures. Add mixtures can be preserved by addition of 4000 ppm of this product 4.0 lb. of this product per 1000 lbs. of add mixture.)

FOR THE PRESERVATION OF AQUEOUS ANALYTICAL AND DIAGNOSTIC REAGENTS USED IN CHEMICAL AND CLINICAL ANALYSIS: Addition of up to 5000 ppm of this product can inhibit the growth of bacteria and fungi in aqueous analytical and diagnostic reagents (5 lbs. of this product per 1000 lbs. of reagent).

TO INHIBIT THE GROWTH OF FUNGI IN GYPSUM WALLBOARD: Addition of up to 38,400 ppm of this product (38.4 lbs of product per 1000 lbs of the formulation, i.e., wet slurry) will inhibit the growth of fungi. It can be added at any time during the formulation procedure. For example, to control the growth of fungi in Gypsum & Dry Wall add a minimum of 4000 ppm of this product (4.0 lb. of product per 1000 lbs of formulation).

To Control The Growth Of Fungi In Carrageenan Based Gels Used To Produce Solid Air Fresheners. Add 0.12 - 0.4% of this product (0.12 - 0.4 lb./100 lbs. of formulation). Add this product into the gel formulation prior to cooling.

To Inhibit the Growth of Bacteria and Fungi In Dry Wall and Gypsum, Pearlite, Plaster-Like, Mineral Based, or Cellulose Derived Building Materials Used In the Manufacture of Ceilings, Ceiling Tile, Walls and Partitions: Addition of up to 38,400 ppm of this product (38.4 lbs. of product per 1000 lbs. of the formulation, i.e., wet slurry) will inhibit the growth of bacteria and fungi. It can be added at any time during the formulation procedure. Alternatively the product may be added to latex or other types of coating systems routinely applied to the surfaces of walls, ceiling tiles, partitions, etc. at the same dosage as above.

LEATHER: This product is used at treatment rates of 0.08% to 4.0%, based on the weight of the leather stock, to prevent the bacterial or fungal degradation of hides and skins. Application level is dependent on the type of hide or leather to be protected, the length of protection desired and the presence of other constituents in the processing formula. The optimum addition should be determined by trial for each individual application. For soaking raw hides this product should be added to the water to be used for soaking. For treating hides cured with dry salt, this product should be applied to the hides or should be mixed with the salt before it is applied to the hides. This product can be used for the protection of wet leather stock such as pickled, chrome, chrome alternative, metal free, and vegetable tanned leathers from mold and mildew during in-tannery wet processing and for the protection of wet-blue during long storage and transportation times. Treatment rates should be calculated based on the wet white weight or wet blue weight, and compatibility with chrome solutions or other treatment chemicals should be confirmed prior to trial.

SODIUM OMADINE® PRODUCT LICENSING & PATENT NOTICE: The SODIUM OMADINE® product may be used in paints with zinc oxide in accordance with the label and composition and method claimed in U.S. Patent 5,518,774 and European Patent 0807152, and their other corresponding foreign patents. Purchase of this product from Lonza, Inc. gives the purchaser a nonexclusive license to use this product in the composition and method claimed in the above-mentioned patents, and the royalty for this license is incorporated into the purchase price of the product.