



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

89265-1

Date of Issuance:

4/15/16

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

NOXILIZER NO₂ STERILANT

Name and Address of Registrant (include ZIP Code):

Noxilizer, Inc.
1450 South Rolling Road
Baltimore, MD 21227

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 unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Signature of Approving Official:

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II,
Antimicrobials Division (7510P)

Date:

4/15/16

3. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 89265-1.”
4. Submit one copy of the revised 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 these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. 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 06/28/2013

If you have any questions, please contact Lorena Rivas by phone at 703-305-5027 or via email at rivas.lorena@epa.gov

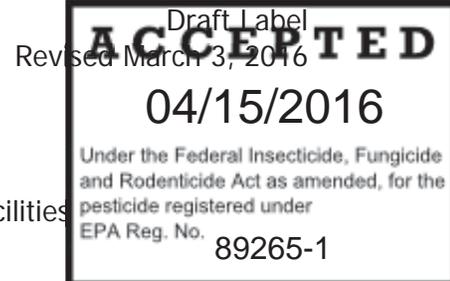
Sincerely,



Jacqueline Hardy, Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: Stamped Label
Product Chemistry Review dated 12/03/2013
Efficacy Review dated 01/23/2015
Revised Risk Assessment dated 02/11/2016

Noxilizer NO₂ Sterilant
 EPA File Symbol 89265-1



NOXILIZER NO₂ STERILANT
 Industrial Sterilant

For Use in Industrial, Commercial and Institutional Facilities

<u>Active Ingredient:</u>	
Dinitrogen Tetroxide/Nitrogen Dioxide (N ₂ O ₄ /NO ₂)	99.5%
<u>Other Ingredients:</u>	0.5%
<u>Total:</u>	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUCION AL USUARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta la haya sido explicada ampliamente. (PRECAUTION TO THE USER: If you do not understand this label, find someone to explain it to you in detail.)

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for at least 15 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 on skin	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for at least 15 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, if possible. • Administer supplemental oxygen with assisted ventilation, if trained to do so. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • 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.
<p>Note to Physician: For inhalation, consider oxygen. Avoid gastric lavage or emesis.</p>	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 Monday through Friday, 7:30 am to 3:30 pm Pacific Time. During other times, call the poison control center at 1-800-222-1222.</p>	

See [Side] {or} [Back] {or} [Other] Panel[s] for Precautionary Statements

EPA Reg. No. 89265-1
 EPA Est. No. _____
 Net Weight: _____
 Lot No. _____ {will appear on label or container}

Manufactured For:
 Noxilizer, Inc.
 Baltimore, MD

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. May be fatal if inhaled. Do not breathe vapor or spray mist. Wear protective eyewear, long-sleeved shirt, long pants, shoes and socks, and chemical-resistant gloves. 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.

PHYSICAL/CHEMICAL HAZARDS

Strong oxidizing agent. Keep away from heat, flame, sparks or hot surfaces. Do not allow sources of ignition near the sterilization/fumigation area. Use only in closed system. Close valve when not in use and when empty. Use in accordance with use directions on the label and in manuals accompanying the sterilization equipment. Ground all equipment, including containers, to avoid static sparks.

LEAK: Evacuate area and keep personnel upwind. When liquid is present and/or the concentration of the vapor in the breathing zone approaches or exceeds 1 ppm NO₂, SCBA respiratory protection is required. Prevent spillage from entering drains. Shut off all possible sources of ignition and increase ventilation. No smoking or naked lights within the area. Stop the leak if safe to do so. Do not exert excessive pressure on the valve; do not attempt to operate a damaged valve. Absorb or cover spill with inert material; carefully contain and neutralize with slaked lime. Collect residuals in a sealed and labeled container for disposal. After cleanup, decontaminate protective gear and clothing by soaking in 5% soda ash solution for at least 24 hours. Rinse and dry.

FIRE: NOXILIZER NO₂ STERILANT will accelerate the burning of combustible materials.
Extinguishing Media: Choose the appropriate media for the surrounding fire. Water contact with the liquid will create toxic vapors. Stop the flow of gas if it can be done without risk. Move the cylinder away from fire if it can be done without risk. Apply cooling water to the cylinder when exposed to flames. Chemical protective clothing that is safe for use with nitric acid in a fire should be worn. When liquid is present and/or the concentration of the vapor in the breathing zone approaches or exceeds 1 ppm NO₂, SCBA respiratory protection is required. Isolate the area until the vapors have dispersed.

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 Pollution 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.

Personal Protective Equipment

All handlers must wear at a minimum:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Protective eyewear
- Chemical-resistant gloves, and

- The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements (including 29 CFR §1910.1047 and 29 CFR §1910.134) under routine and reasonably foreseeable emergency situations.

When handlers could have eye or skin contact with liquid NO₂ solutions, such as during maintenance and repair, changing sterilant cylinders, or cleaning up spills, they must wear:

- Chemical-resistant attire, such as an apron, protective suit, or footwear that protects the area of the body that might contact liquid NO₂, and
- Face-sealing goggles, a full-face shield, or a full-face respirator.

Follow the respirator manufacturer's user's instructions for changing cylinders.

Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29 CFR §1910.134).

- An operational calibrated NO₂ detector must be present within 5 feet of the equipment and should alarm at no more than 1 ppm NO₂. The user facility should have an emergency evacuation plan in case of an NO₂ leak or spill.

Directions for Use:

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

NOXILIZER NO₂ STERILANT is a sterilant solution containing liquid nitrogen dioxide (liquid NO₂). Upon use, gaseous nitrogen dioxide is released.

NOXILIZER NO₂ STERILANT may be used to sterilize laboratory equipment, isolators, medical devices (e.g. dressing forceps, hemostatic forceps, sponge forceps, surgical reference rulers and markers, needle holders) pharmaceuticals and pharmaceutical production equipment. NOTE: Not for use for sterile reprocessing of reusable medical devices.

NOXILIZER NO₂ STERILANT may only be used with Noxilizer produced or licensed equipment and can only be applied via a closed system. NOXILIZER NO₂ STERILANT may be used only with the following types of equipment:

- Noxilizer-branded Sterilizers explicitly labeled for use with NOXILIZER NO₂ STERILANT.
- Nitrogen Dioxide generators, licensed by Noxilizer for use with NOXILIZER NO₂ STERILANT and specifically labeled for use with NOXILIZER NO₂ STERILANT, for delivery of sterilant into a validated and properly maintained sealed separative device¹ (e.g., glove boxes, isolators) with an outward hourly leak rate of no greater than 1% (equivalent to a class 3 isolator, per ISO 14644–7:2004²).

¹A separative device is defined as equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume. NOTE: Some industry-specific examples of separative devices are clean air hoods, containment enclosures, gloveboxes, isolators and mini-environments. From EN ISO 14644–7:2004 Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and minienvironments)

²The defined maximum hourly leak rate for a Class 3 separative device (*i.e.*, <1% per hour) is per EN ISO 14644–7:2004, Appendix E, Table E-1.

Sterilization units using NOXILIZER NO₂ STERILANT must include a scrubber system containing sodium permanganate or equivalent to neutralize exhaust nitrogen dioxide. Any exhaust gas from the use of this product must be discharged to the outdoor environment through the ventilation system in the facility. Do not recirculate any exhaust gas.

NOXILIZER NO₂ STERILANT must be applied under the following conditions:

- Humidity: 75 % or greater
- NO₂ Concentration: 20 mg/L
- Contact Time: 90 minutes or greater
- Air Exchanges: 5 or greater

Safety and awareness training is required for all employees who may be exposed to the sterilant, and a copy of the MSDS must be available to all employees. Personnel handling the sterilant cylinders must be trained on safe handling of the canisters, and personnel operating the equipment must be trained on safe handling of the canisters and operation of the equipment.

NOXILIZER NO₂ STERILANT may be used only in accordance with the instructions in the Noxilizer equipment Operations Manual. Use must also be in accordance with the instructions for the specific equipment with which the sterilant is used. Users must read and follow the instructions in the Operator Manuals for the Sterilant and for operation of the equipment.

An operational calibrated NO₂ detector must be present within 5 feet of the equipment and should alarm at no more than 1 ppm NO₂. The user facility should have an emergency evacuation plan in case of an NO₂ leak or spill.

To be used only by persons experienced in Noxilizer sterilization and fumigation, or by persons under direct supervision of persons who are experienced in Noxilizer sterilization and fumigation. Use only in accordance with the directions and the safety precautions listed on the label, operator manuals, and the current Noxilizer Safety Data Sheet for NOXILIZER NO₂ STERILANT.

- Always check cylinder valves and for leaks before moving cylinder into your facility.
- The approximate vapor pressure exerted by this gas mixture will be 0 psig (0 kg/cm²) at 70°F (21.1 °C) while liquid is present. Vapor pressure will be higher if temperature is above 70°F (21.1°C); lower if temperature is below 70°F (21.1°C).

NOTE: At sea level, the boiling point of the NOXILIZER NO₂ STERILANT is 21.15°C, which results in a vapor pressure of 1 atmosphere, or 0 psig. A reading of 0 psig (or less) on a pressure gauge attached to the NOXILIZER NO₂ STERILANT cylinder **does not** indicate an empty cylinder.

- Cylinder must be in an upright position when discharging. Cylinder must be secured to prevent falling over.
- Discharge valve outlet is provided with a stainless steel CGA 660 or CGA 180 connection.
- Remove protective valve cap and make sure valve threads are undamaged.
- The connection to the cylinder valve should be a stainless steel CGA 660 or CGA 180 connector. Use of other metals could result in corrosion and eventual leaks within the system.
- Use a Teflon washer at the point of connection to provide a tight seal.

- All piping and fittings should be stainless steel, capable of withstanding the pressure to be encountered. Do not use rubber or plastic materials (other than the Teflon washer or Teflon tape at threaded joints). Install relief devices where liquid can be trapped between valves.
- To open cylinder valve, turn hand wheel counterclockwise. Do not use a wrench or other leverage device to open or close cylinder valve.
- Use with adequate general and local ventilation.