UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 8, 2025

Cinda Bell
Regulatory Agent for,
Biolene S.R.L.
Electronic Transmittal: Cbell@scireg.com

Subject: Label Amendment – To add the text required by the ethylene oxide RED
Product Name: Biolene BX
EPA Registration Number: 73711-5
Received Date: February 10, 2020
Action Case Number: 00220001

Dear Ms. Bell:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. Pursuant to 40 CFR 156.10(a)(6) you must submit one 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 wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2). 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) lists 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, FIFRA section 12(a)(1)(B). 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 Assurance.
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen Leavy by phone at (202)-566-0668, or via email at Leavy.Karen@epa.gov.

Sincerely,

Luisa C. Samalot-Freire, Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510M)
Office of Pesticide Programs
U.S. Environmental Protection Agency

Enclosure: stamped label

BIOLENE TM

BX A

-------- Will be 100, 127 or 170

Active Ingredient: Ethylene Oxide 100%- Net wt. B

--------- will be 100g, 127 g or 170 g

KEEP OUT OF REACH OF CHILDREN

DANGER PELIGRO

PRECAUCION AL USUARIO: Si usted no lee Ingles, no use este producto hasta que la etiqueta le haya sido explicada ampliamente.

ACCEPTED

05/08/2025

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 73711-5

KEEP OUT OF REACH OF CHILDREN
DANGER
EXTREMELY FLAMMABLE - DO NOT USE NEAR FLAME
CAUSES EYE AND SKIN BURNS. MAY CAUSE NERVOUS SYSTEM DAMAGE
CANCER HAZARD AND REPRODUCTIVE HAZARD

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene Oxide (29 CFR 1910.1047).

SEE PACKAGE INSERT FOR DIRECTIONS FOR USE, STORAGE AND DISPOSAL AND ENVIRONMENTAL HAZARDS.

FIRST AID

IN ALL CASES OF OVEREXPOSURE GET MEDICAL ATTENTION IMMEDIATELY. TAKE PERSON TO A DOCTOR OR EMERGENCY TREATMENT FACILITY AT ONCE.

IF INHALED - Move person to fresh air. Keep warm. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. If breathing is difficult, give oxygen. Call a poison control center or doctor for further treatment advice, even if there are no symptoms. Keep under medical observation – symptoms may be delayed.

IF ON SKIN OR CLOTHING– Take off contaminated clothing and shoes. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. Aerate, wash or clean contaminated clothing and discard leather goods.

IF SWALLOWED – Call poison control center or doctor immediately for treatment advice. Have person sip two glasses of water if able to swallow. Do not induce vomiting. Do not give anything by mouth to an unconscious person.

IF IN EYES - Hold eye open and rinse slowly and gently with water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

HOTLINE NUMBER- Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Biolene at (54 11) 4308 4963.

NOTE TO PHYSICIAN - Skin exposure to Ethylene Oxide will commonly result in skin irritation with extensive blister formation. At high concentrations, severe conjunctivitis can occur. Irritation of the respiratory tract may occur, but without acute lung edema. Symptoms of systemic intoxication are headache, nausea, vomiting, incoordination, and cardiac irregularities. Treatment is symptomatic

Made in Argentina BIOLENE S.R.L. – Saavedra 870 Alt. Km 20.700 (Ruta 21) – Pontevedra (B1761BWN) Merlo, Buenos Aires, Argentina. Tel: (+54-220) 404-1501, (+54-11) 3220-8011/12
E-mail: info@biolene.com Website: www.biolene.com

Use Only in Accordance with Manufacturer's instructions in a validated Sterilizer.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER! CAUSES EYE AND SKIN BURNS. HARMFUL IF INHALED. MAY CAUSE NERVOUS SYSTEM DAMAGE.

DANGER! CANCER HAZARD AND REPRODUCTIVE HAZARD.

EFFECTS OF OVEREXPOSURE: May be fatal if inhaled in high concentrations. May cause irritation of the respiratory tract, chest tightness, headache, nausea, vomiting, diarrhea, light-headed feeling, dizziness, weakness, drowsiness, cyanosis, loss of coordination, convulsions, coma, delayed lung injury (fluid in the lungs), immediate or delayed skin irritation or blisters, allergic skin reaction.

OTHER POSSIBLE DELAYED HEALTH EFFECTS:
May cause nervous system injury, cataracts, adverse reproductive effects, chromosomal and mutagenic changes, and cancer.

PEL: 1 PPM TWA (as per the Ethylene Oxide Standard 29 CFR 1910.1047).
EL: 5 PPM - excursion limit 15 minutes.
ODOR: Ether-like at high concentrations. Exposure to toxic levels may occur without warning to or detection by the user.

PRECAUTIONS - Do not breathe vapor. Do not swallow. Do not get in eyes, on skin, or on clothing. Store and use with adequate ventilation in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047).

PHYSICAL OR CHEMICAL HAZARDS:
DANGER! - HIGHLY FLAMMABLE LIQUID AND GAS UNDER PRESSURE.

Contents under pressure. Do not use near flame, sparks, hot surfaces, or allow sources of ignition near the sterilization/fumigation area. Ethylene Oxide is extremely flammable and reactive. Ground all equipment (including this container) to prevent sparks.

INSERT THIS END - INTRODUCIR POR ESTE LADO

LEAK - In case of leak evacuate area and keep personnel upwind. Shut off all sources of ignition. Use self-contained breathing apparatus and protective clothing and shut off leak if without risk.
FIRE - In case of fire move container away from fire if without risk. Use water spray or fog nozzle to keep container cool.

BIOLENE TM

BX A

-------- Will be 100, 127 or 170

Active Ingredient: Ethylene Oxide 100%- Net wt. B

--------- will be 100g, 127 g or 170 g

Personal Protective Equipment (PPE).
Some materials that are chemical-resistant to this product are Teflon, polyethylene, polypropylene and glass. If you want more options, follow the instructions for category A on an EPA chemical-resistance category selection chart.
All handlers must wear at a minimum:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical resistant gloves, and
- when the ambient ETO concentration is 1 to 50 ppm, full-facepiece respirator with ETO approved canister, front or back mounted,
- when the ambient ETO concentration is 50 to 2,000 ppm, (1) positive-pressure supplied-air respirator equipped with full-facepiece, hood, or helmet; or (2) continuous-flow supplied-air respirator (positive-pressure) equipped with hood, helmet, or suit,
- when the ambient ETO concentration is >2,000 ppm or unknown (e.g., emergency situations), (1) positive-pressure self-contained breathing apparatus equipped with full-facepiece; or (2) positive-pressure full-facepiece supplied-air respirator equipped with an auxiliary positive-pressure self-contained breathing apparatus.

When handlers could have eye or skin contact with ETO or ETO solutions, such as during maintenance and repair, vessel cleaning, 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 ETO or ETO solutions, and face-sealing googles, a full-face shield, or a full-face respirator.

USER SAFETY REQUIREMENTS
1. Follow the respirator manufacturer's user's instructions for changing canisters.
2. Respirators must be fit-tested and fit-checked using a program that conforms to OSHA's requirements (see 29 CFR Part 1910.134).
3. Respirator users must be trained using a program that confirms to OSHA's requirements (see 29 CFR Part 1910.134).
4. Respirator users must be examined by a qualified medical practitioner to ensure physical ability to safely wear the style of respirator to be worn. A qualified medical practitioner is a physician or other licensed health care professional (PLHCP) who will evaluate the ability of a worker to wear a respirator.
The initial evaluation consists of a questionnaire that asks about medical conditions (such as a heart condition) that would be problematic for respirator use. If concerns are identified, then additional evaluations, such as physical exam, might be necessary. The initial evaluation must be done before respirator use begins. It does not need to be repeated unless the health status or respirator use conditions change (see 29CFR Part 1910.134).

USER SAFETY RECOMMENDATIONS: Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, 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. Users should remove clothing/PPE immediately if pesticide gets inside. The wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: Do not discharge effluent containing this product into lakes, streams,

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. It is the employer´s responsibility to follow the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). This product may be used only in facilities that meet the requirements of the Ethylene Oxide Standard (29 CFR 1910.1047). This product may be used only in vacuum or gas-tight chambers designed for use with 100% ethylene oxide. This product may be used only by persons who have been trained in accordance with the Ethylene Oxide Standard (29 CFR 1910.1047). When used to sterilize health care items, this product must be used in ethylene oxide gas sterilizers that have FDA clearance.

1. AS A STERILANT AND FUMIGANT GAS:
A. For complete use directions (including type of surfaces, objects, or items/products recommended for treatment, pre-cleaning instructions, concentration of gas per unit volume of closed space to be treated, exposure time/temperature, relative humidity, ventilation/aeration time, and method of monitoring to be used) refer to the ethylene oxide gas sterilizer manufacturers' Operators Manuals.
This product may be used only to sterilize medical or laboratory items, pharmaceuticals, and aseptic packaging, (see 21 CFR 201.1(d)(5)), or to reduce microbial load on cosmetics, artifacts, and archival material or library objects.
B. In Hospitals and Healthcare facilities, as well as in contract sterilization facilities, including facilities treating medical equipment and supplies, musical instruments, library/museum artifacts, cosmetics, and spices the following requirements must be followed: Sterilization/fumigation with ETO must be performed only in vacuum or gas tight chambers designed for use with ETO. After February 28, 2010, a single chamber process is required for ETO treatment (sterilization and aeration are to occur in the same chamber) in hospitals and healthcare facilities. Safety and awareness training is required for all employees including office staff. Information and training must be provided to all employees in the facility at the time of initial assignment and annually thereafter. The safety training must include, at a minimum, the following information:
1. the most recent monitored ambient levels of ETO in the facility;
2. The potential health effects from the levels of ETO in the facility;
3. the emergency response plan and how to respond in an emergency;
4. the availability of the Material Safety Data Sheet and other materials related to the health hazards of exposure to ETO.
In order to reduce ambient levels of ETO, lengthy facility aeration is encouraged. Achieving an ambient level of 0.25 ppm (measured as a daily time-weighted average) greatly reduces potential long-term risks to employees not directly involved in the ETO applications.
Air monitoring should include the entire facility including office space, break areas, and loading/unloading areas.

C. Ethylene Oxide cycle parameters depend on several sterilizing/fumigating variable factors: pre-conditioning (if any); exposure time; chamber air pressure; gas concentration; types and quantities of items to be sterilized/fumigated; packaging; load configuration in the chamber; microbial challenge method; desired degree of disinfection; and the desired performance of the sterilized/fumigated product and package.
D. The sterilization/fumigation cycle parameters should be those prescribed by the equipment manufacturer. If other cycle parameters are used, the safety and efficacy of the alternate cycle parameters must be validated and are the responsibility of the user.

ponds, estuaries, oceans or other waters unless in accordance with requirements of 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.	NEVER USE PARAMETERS WHICH ALLOW FLAMMABLE MIXTURES OF ETHYLENE OXIDE AND AIR TO ENTER THE CHAMBER

STORAGE AND DISPOSAL Do not contaminate food, feed, or water by storage and disposal. **PESTICIDE STORAGE.** Use in accordance with tag attached to valve. Store in cool, well-ventilated area. Avoid exposure to heat or direct sunlight as may cause polymerization. **PESTICIDE DISPOSAL.** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray, or mixture of rinsate is a violation of Federal Law. Unwanted or expired ampoules should be returned to the manufacturer for disposal. Contact Biolene S.R.L. Tel no. 54-11-4308-4963 for instructions. If unwanted or expired ampoules cannot be disposed of according to Control Agency, call a Hazardous waste representative at the nearest EPA Regional Office for guidance. **CONTAINER DISPOSAL.** Do not reuse empty box, empty ampoules, or liner bags. Wrap box, ampoules and bags in paper and discard in the trash. **SHELF LIFE**: Shelf life is two years from date of manufacture as printed on the cartridge.	