

73711-5

10-31-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 73711-5
Date of Issuance: OCT 31 2007

Term of Issuance: Conditional

Name of Pesticide Product: Biolene BX

NOTICE OF PESTICIDE:
 Registration
 Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Biolene S.R.L.
Constitucion 2610
Buenos Aires, Argentina C1254AAR

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration 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/reregistered 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 sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
 - a.) Revise the "EPA Registration Number to read, "EPA Reg. No. 73711-5".

Signature of Approving Official:

Velma Noble
Velma Noble

Product Manager Team-31
Regulatory Management Branch I
Antimicrobials Division (7510C)

Date:

OCT 31 2007

CONCURRENCES

SYMBOL	SURNAME	DATE
EPA REG. NO. 73711-5		

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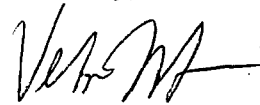
3. The alternate brand names, Biolene BX-100, Biolene BX-127, and Biolene BX-170, are acceptable.

A stamped copy of the label is enclosed for your records. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Should you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

BIOLENE™

BX **A** →

A will be 100, 127 or 170

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

B will be 100g, 127g or 170g

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.

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. - Constitución 2610 - C1254AAR - Buenos Aires - Argentina
Tel: (54 11) 4308-4963 /5652 Fax: (54 11) 4941-0346

EPA Reg No. _____
EPA Est. No. _____

INSERT THIS END - INTRODUCIR POR ESTE LADO



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

ACCEPTED

OCT 31 2007

Use Only in Accordance With Manufacturer's
Instructions in a validated Sterilizer.

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

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.

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.

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BIOLENE™BX **A** → **A**

will be 100, 127 or 170

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

will be 100g, 127g or 170g

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 Pollutant Discharge Effluent 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.

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, and artifacts, archival material or library objects.

B. Sterilization/fumigation with Ethylene Oxide must be performed only in vacuum or gas tight chambers designed for use with Ethylene Oxide.

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.

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.