

75512-2

2-9-2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:
75512-2

Date of Issuance:
FEB 9 2007

Term of Issuance:
Conditional

Name of Pesticide Product:
Ebiox TruKleen Spray

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Ebiox Ltd.
2301 Rosecrans Ave., Suite 3180
El Segundo, CA 90245

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. 75512-2".

Signature of Approving Official:

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

Date:

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b) Delete the claim, "Cleans to the molecular level" because this claim has not been scientifically identified.

c) Since the label supports container sizes less than 1 gallon, revise the "Storage and Disposal" statements must support the following labeling in accordance with PR Notices 84-1:

Containers 1 gallon or less

Storage and Disposal: Store cool dry place and in original container in areas inaccessible to children. Do not reuse empty container. Wrap and discard in trash or offer for recycling if available.

d) Delete the third bullet under the "Marketing/Label Claims" because it appears as the first paragraph under the "Directions for Use." Also, delete the organism, *S. aureus* (GRSA) because data was not submitted to support it.

e) Move the 4th, 9th, 12th, 45th, and 46th bullets under the "Marketing/Label Claims" and place them in the 4th paragraph under the "Directions for Use." Revise these bullets to be in agreement with PR Notice 2000-5, Mandatory Labeling, by deleting "recommended" and stating "For Use."

f) Claims regarding the absence of an ingredient are considered misleading statements (40 CFR 156.10 (a)(5)(i) and/or 40 CFR 156.10 (a)(5)(viii)) and unacceptable. Therefore, you must delete the 7th and 43rd claims under "Marketing/Label Claims."

g) Delete the 42th claim under "Marketing/Label Claims" because these statements are incomplete and misleading. Specific Use directions may be added to the label indicating how surgical/critical instruments and equipment may be disinfected or cleaned prior to Sterilization.

h) Under the "Directions for Use," revise the second paragraph by adding "barber and beauty salons, homes, farms, and poultry houses."

i) Since this product makes cleaning claims, the directions must be revised to support the claim by stating:

General Cleaning: Dilute 2.6 oz per gallon of water. Apply use dilution with spray bottle, cloth, sponge, mop until surfaces are thoroughly wet. Wipe or allow surfaces to air dry.

j) Under "Combination Cleaning/Disinfecting," add the statement, "Do not use on utensils, glasses, dishes, or interior surfaces of appliances," as the last sentence for the 4th bullet.

k) Add the following Fungicidal labeling:

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Fungicidal Activity: Ebiox TruKleen Spray is an effective fungicide against *T. mentagrophytes* (agent causes Athlete's Foot Fungus) when used in areas such as health spas, and shower and bath areas, health spas. Follow disinfection directions.

l) Add the following Mold and Mildew labeling:

Mold and Mildew Control: Ebiox TruKleen Spray will effectively inhibit the growth of mold and mildew and odors caused by them when applied to hard nonporous surfaces. Follow disinfection directions. Repeat treatment every seven days, or more often if new growth appears.

m) Revise the proposed HIV directions to be in compliance with the Agency's HIV Labeling Policy (Federal Register Vol. 54 No. 26 dated February 9, 1989) by stating:

KILLS HIV-1 AND/OR HBV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) and/or Hepatitis B Virus.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND/OR HBV ON SURFACES/OBJECTS WITH BLOOD/BODY FLUIDS

Personal Protection: Clean-up should always be done wearing protective latex gloves, gowns, masks, and eye protection

Cleaning Procedure: Blood and other body fluids containing HIV must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Leave surface wet for 5 minutes. Use a 10 minute contact time for Adenovirus.

Disposal of Infectious Materials: Blood, body fluids, cleaning materials, and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

n) Revise the "Poultry House and Farm Premise" directions as follows:

1. Remove all *animals (poultry)* and feeds from premises, *vehicles*, trucks, coops, *enclosures*, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by *animals (poultry)*.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with spray for a period of 10 minutes.

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6. *Disinfect all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure.*
7. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

o) Since this product can be used in veterinary facilities, add the following directions:

Veterinary Facilities: For cleaning and disinfecting hard nonporous surfaces and equipment used for animal food and water, utensils, instruments, cages, kennels, stables, and catteries.

1. Remove animals and feeds from premises, animal transportation vehicles, crates, etc.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces for a period of 10 minutes.
6. Disinfect all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

p) Add "**Vehicle**" disinfection directions that read "Treat all vehicles including mats, crates, cabs, and wheels. Apply spray thoroughly wetting surfaces. Allow to remain wet for 10 minutes. Wipe dry or let surfaces air dry.

3. The cited primary eye irritation study is acceptable.
Ebiox TruKleen Spray's Acute Toxicology Profile:

Acute Toxicology Study	Toxicity Category
Acute Oral	IV
Acute Dermal	IV
Acute Inhalation	IV
Primary Eye Irritation	II
Primary Skin Irritation	III
Dermal Sensitization	Non-sensitizer


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4. 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

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Storage and Disposal

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

Pesticide Storage: Store in a cool dry place.

Container Disposal: Do not reuse empty container. Place in trash or offer for recycling if available.

Product Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

- Intended for use in ((healthcare) settings such as) hospitals, outpatient surgery centers, clinics, medical and dental offices, laboratories, (isolation areas) (emergency departments) (veterinary facilities) (ambulances) (police and fire vehicles) (jails) (detention centers) (hotels) (schools) (industrial clean rooms) (health spas) (day care facilities) and areas where control and prevention of cross-contamination is critical
- Multi-purpose, fast acting technology cleans, disinfects and eliminates odors in one easy step
- Effective against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Methicillin Resistant Staphylococcus aureus (MRSA)*, *Gentamicin Resistant Staphylococcus aureus (GRSA)*, *Herpes Simplex Type 1*, *Hepatitis B*, *Human Immunodeficiency Virus (HIV)*, *Human Coronavirus*, *Adenovirus 5*, and *Trichophyton mentagrophytes (Athlete's Foot fungus)*
- [REDACTED] for use on any hard, non-porous, environmental surfaces such as counter tops, floors, walls, tables, chairs, bed frames, plastic covered mattresses, sinks, carts, cabinets, lights, etc.
- Bactericidal, Virucidal and Fungicidal
- Can be used in critical care areas
- [REDACTED]
- Prevents mold and mildew
- [REDACTED] for use on any hard, non-porous, surfaces such as counter tops, floors, walls, tables, the outside of microwaves, refrigerators, stoves, sinks, trash cans, diaper pails, glazed tubs and tile, computers, phones, non-wooden patio furniture, etc.
- Handles all daily clean-up jobs fast
- The smart way to clean and disinfect (Poultry Houses) (Farms)!
- [REDACTED] for use on any hard, non-porous, surfaces such as counter tops, floors, walls, tables, the sinks, trash cans, glazed tubs, tile, feed racks, troughs, automatic feeders, fountains, and waterers etc.
- Bactericidal
- Virucidal
- Fungicidal
- Cleans
- Disinfects
- (Multi) purpose
- (Multi) surface(s)
- Triple (action) formula (cleans) (disinfects)
- Leaves your (kitchen) (bathroom) (patio) (clean) (and) (fresh)
- Easy to use
- For (light touch ups) (quick clean-ups) (in one easy step)

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- For most household surfaces (around the house)
- Great for cleaning around (kitchen) (bathroom) (office) (dining room) (children's room) (office) (patio)
- (Great for) Light (heavy) duty jobs
- Makes (your job) (cleaning) (easier) (easy) (faster)
- One step disinfecting (cleaning)
- Saves (you) time cleaning
- The (easy) (fast) (smart) (way to) (disinfect) (clean)
- Cuts grease
- Kills (Household) (germs) (bacteria)
- Cuts grime
- Streak Free
- Cuts through (tough) grease)
- Antibacterial multi-surface cleaner
- Heavy duty (multi- purpose) cleaner
- Not intended for polished or bare wood surfaces
- Unplug small electrical equipment before use
- (For) (product information) (or technical information) (questions) (comments) (call) (contact) Ebiox at 888-335-4234 (or visit our) website (at) www.ebiox.com
- Effective against a wide range of microorganisms

• [REDACTED]
 • [REDACTED]
 • [REDACTED]
 • [REDACTED]
 • [REDACTED]

- Cleans most household surfaces fast
- Additional [REDACTED] non-porous surfaces such as stainless, metal(s), glazed ceramic tile, porcelain, hard plastics, glass, plastics, non-porous vinyl
- Note optional surfaces that may be used on labels: Interior and exterior surfaces of infant incubators, basinets, cribs and warmers, infant/child care equipment surfaces, changing tables, oxygen hoods, Exterior surfaces of anesthesia machines, respiratory care equipment surfaces, patient monitoring equipment, exterior surfaces of medical device equipment, diagnostic equipment, operating room tables and lights, laboratory equipment and surfaces, IV poles, physical therapy equipment surfaces, drained whirlpool tanks surfaces, bathing stretchers, spine back boards, ambulance equipment surfaces, gurneys, stretchers, examination table surfaces, countertops, exterior toilet bowl surfaces, sinks, exterior surfaces of refrigerators, floors, walls, stoves, dental chairs, dental office equipment surfaces, dental operating room suite exterior surfaces, dental chairs, stools, animal cage surfaces, veterinary animal care surfaces, weight lifting equipment surfaces, computer workstations, keyboards, handrails, door knobs, bed railings, shower stalls, bath tubs, cabinets, countertops, tanning bed surfaces, hair clippers, scissors, trash cans, toys
- Intended for use in ((healthcare) settings such as) (hospitals) (outpatient surgery centers) (recovery rooms) (radiology treatment areas) ((medical (offices) (and) dental (offices)) (laboratories), (isolation areas) (emergency departments) (veterinary facilities) (ambulances) (police and fire vehicles) (jails) (detention

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centers) (hotels) (schools) (industrial clean rooms) (health spas) (day care facilities) (home health agencies) (daycare centers) (and areas where control and prevention of cross-contamination is critical

- Patent Pending
- REORDER CODE: USETCXX-P

DIRECTIONS FOR USE

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

This product is effective against the following organisms: *Staphylococcus aureus* (Staph), *Salmonella enterica* (Salmonella), *Pseudomonas aeruginosa* (Pseudomonas), *Methicillin Resistant Staphylococcus aureus* (MRSA), *Gentamicin Resistant Staphylococcus aureus* (GRSA), *Herpes Simplex Virus Type 1*, *Hepatitis B*, *Human Immunodeficiency Virus (HIV)*, *Human Coronavirus*, *Avian Influenza Virus*, *Adenovirus 5*, and *Trichophyton mentagrophytes* (Athlete's Foot fungus)

This product is Intended for use in (healthcare) settings such as hospitals, outpatient surgery centers, clinics, medical and dental offices, laboratories, (isolation areas) (emergency departments) (veterinary facilities) (ambulances) (police and fire vehicles) (jails) (detention centers) (hotels) (schools) (industrial clean rooms) (health spas) (day care facilities) and areas where control and prevention of cross-contamination is critical

{For labels that list medical premises and metal and/or stainless steel surfaces :} This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in direct contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

This product is [redacted] for use on any hard, non-porous, surfaces such as counter tops, floors, walls, tables, the outside of microwaves, refrigerators, stoves, sinks, trash cans, diaper pails, glazed tubs and tile, computers, phones, non-wooden patio furniture, etc.

Combination Cleaning and Disinfecting of Hard, Non-porous Surfaces:

- For heavily soiled areas a pre-cleaning step is required.
- (Remove safety seal and) spray soiled area and allow surface to remain (visibly) (thoroughly) wet for 5 minutes (10 minutes for Adenovirus).
- ((Then) (Wipe dry) (or) let (surface(s) (air) dry)).
- For food contact surfaces such as counters and tables, rinse or wipe surface with potable water.

On painted surfaces, test a small area first.

Special Instructions for Cleaning and Decontamination Against HIV (AIDS Virus) on Surfaces/Objects Soiled with Blood/Body Fluids:

- o **Personal Protection:** [redacted] e, wear disposable protective equipment such as gloves, gowns, masks or eye coverings should be used.
- o **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned surfaces can be disinfected [redacted] e. [redacted] ose.
- o **Contact Time:** [redacted] allow to remain (visibly) (thoroughly) wet for 5 minutes. (Then) (wipe) (dry) (clean) (or) let (surface(s) (air) dry)).
- o **Disposal of Infectious Waste:** [redacted] n accordance with Federal, State and local regulations for infectious waste disposal.

For Disinfection of hard, Non-Porous Bath and Therapy Equipment (Whirlpool Units): After using the whirlpool unit, drain and refill with this product (product name) to just cover the intake valve. Start the pump to circulate the solution. Wash down the unit sides, seat of the chair, lift and all related equipment with a clean swab, brush or sponge. Treated surfaces must remain wet for 10 minutes. After the unit has been thoroughly cleaned, drain the use-solution from the unit and rinse any cleaned surfaces with fresh water. Repeat for heavy coiled units.

Disinfection of Salon/Barber Instruments and Tools: Immerse pre-cleaned barber/salon tools (combs, brushes, razors, manicure/pedicure tools, clippers, scissors, trimmer blades) in this product (product name) per for at least 10 minutes. Rinse instruments thoroughly and dry before reuse. A fresh use-solution should be

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prepared daily or more often if the use solution becomes cloudy or soiled. Note: Plastics may remain immersed until ready to use. Stainless steel shears and instruments must be removed after 10 minutes, rinsed, dried and kept in a clean non-contaminated receptacle. Prolonged immersion may cause damage to stainless steel or metal instruments.

For Disinfection of Poultry Premises and Farms

1. Remove all poultry and feeds from premises, trucks, coops, and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or transversed by poultry.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[REDACTED]

[REDACTED]