

75512-1

4-18-2007

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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:

75512-1

Date of Issuance:

APR 18 2007

Term of Issuance:

Conditional

Name of Pesticide Product:

Ebiox TruKleen Wipes

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. 75512-1".

Signature of Approving Official:

Velma Noble

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

Date:

APR 18 2007

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b) Since the label supports container sizes that are less than 1 gallon or , the "Storage and Disposal" statements must support the following labeling in accordance with PR Notice 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.

c) On page 2, delete the 2<sup>nd</sup> bullet under the "Marketing/Label Claims" because it appears as the first paragraph under the "Directions for Use."

d) On page 2, revise the 9<sup>th</sup> by stating "Kills 99.9% of broad-spectrum bacteria, viruses, and fungi including..." Also, revise the 9<sup>th</sup> and 14<sup>th</sup> claim, by deleting the organism, *S. aureus* (GRSA) because data was not submitted to support it.

e) It is the Agency's policy that featured statements/phrases, special graphics, or any product name that employs or emphasizes/draws attention to the efficaciousness against the virus, Avian Influenza or Bird Flu, are unacceptable. Therefore, you must delete the claim, "Effective against Avian Influenza Virus." Also, revise the nomenclature for Avian Influenza Virus" in the 9<sup>th</sup> and 14<sup>th</sup> bullets as well as the 1<sup>st</sup> paragraph in the "Directions for Use" to read *Avian Influenza Virus H9N2*.

f) On page 2, move the 4<sup>th</sup>, 10<sup>th</sup>, 15<sup>th</sup> bullets as well as the 5<sup>th</sup> and 11<sup>th</sup> bullets on page 3, and incorporate them into the 4<sup>th</sup> 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."

g) On page 3, move the 12<sup>th</sup> bullet and incorporate it into the 2<sup>nd</sup> paragraph under the "Directions for Use."

i) 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 6<sup>th</sup> bullet on page 2 and the 18<sup>th</sup> bullet on page 3.

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

**General Cleaning:** Wipe surface to be cleaned with a towelette. Then wipe dry or allow to air dry:

k) Add the following Fungicidal labeling:

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

l) Add the following Mold and Mildew labeling:

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**Mold and Mildew Control:** Ebiox TruKleen Wipes 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-1AND/ 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) Delete the "Poultry Premises and Farm" disinfection directions because a towelette product does not contain enough use solution to thoroughly disinfect through saturation or immersion large surface areas commonly found in Poultry Premises and Farms.

3. The proposed acute inhalation waiver rationale is acceptable.  
Ebiox TruKleen Wipes 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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Signal Word: **Warning**

The "Precautionary Statements" must be revised to comply with the acute toxicity profile by stating:

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear such as goggles, face shield or safety glasses, protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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  
Efficacy Data Evaluation

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# Ebiox TruKleen™ Wipes

## Broad Spectrum, Fast Acting Disinfecting Wipes

### Active Ingredients:

Alkyl dimethyl benzyl ammonium chloride (50% C <sub>12</sub> , 30% C <sub>14</sub> , 17% C <sub>16</sub> , 3% C <sub>18</sub> ).....	0.499%
Didecyl dimethyl benzyl ammonium chloride.....	0.451%
Poly (iminoimidocarbonyliminoimidocarbonyliminohexamethylene) Hydrochloride (PHMB).....	0.100%
<b>Other Ingredients:</b> .....	<b>98.950%</b>
<b>Total:</b> .....	<b>100.000%</b>

**KEEP OUT OF REACH OF CHILDREN**

### WARNING

See back panel for additional precautionary statements

FIRST AID	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If on skin</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In case of a medical emergency involving this product call the poison control center: 1-800-222-1222.	

EPA Reg. No.: 75512-R  
EPA Est. No.: 9152-CA-1

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

APR 18 2007

**Manufactured for:**  
Ebiox Ltd. (or Limited)  
2301 Rosecrans Ave., Suite 3180  
El Segundo, CA 90245

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

Net Contents: (1) (25) (50) (75) (100) (200) (XX number) Wet Wipe(s) (8 3/4" x 8") 75512-1

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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. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

#### Storage and Disposal

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

**Pesticide Storage:** Store at room temperature.

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

**Product Disposal:** Dispose of used towelettes in the trash after use. Do not flush.

- 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
- Bactericidal and Virucidal
- Recommended for use on any hard, non-porous, environmental surfaces such as counter tops, floors, walls, tables, bed frames, sinks, carts, cabinets, lights, etc.
- Can be used in critical care areas
- Free from alcohol, aldehydes, chlorine, phenols and halogens, phosphorus and bleach
- Prevents mold and mildew
- Multi-purpose, fast acting technology cleans, disinfects and eliminates odors in one easy step
- Kills 99.9% and removes a wide variety of bacteria including: *Staphylococcus aureus* (Staph), *Salmonella enterica* (Salmonella), *Pseudomonas aeruginosa* (Pseudomonas) *Methicillin Resistant Staphylococcus aureus* (MRSA), *Gentamicin Resistant Staphylococcus aureus* (GRSA), *Herpes Simplex Type 1*, *Hepatitis B*, *Human Immunodeficiency Virus* (HIV), and *Adenovirus 5*
- Recommended 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.
- Cleans most household surfaces fast – just pull, wipe and toss!
- The smart way to clean and disinfect!
- 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*, *Avian Influenza Virus*, and *Human Immunodeficiency Virus* (HIV)
- Recommended for use on any hard, non-porous, environmental surfaces such as counter tops, floors, walls, tables, sinks, carts, cabinets, lights, etc.
- Effective against *Avian Influenza Virus*
- Bactericidal
- Virucidal
- 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)
- 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)

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- Cuts grime
- Streak Free
- Cuts through (tough) grease
- Antibacterial multi-surface cleaner
- Additional recommended non-porous surfaces such as stainless, metal(s), glazed ceramic tile, porcelain, hard plastics, glass, plastics, non-porous vinyl
- 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
- Note optional surfaces that may be used on labels: Interior and exterior surfaces of infant incubators, basinet, 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 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
- Disinfection of surfaces which may be contaminated with Adenovirus 5: Spray surfaces allow surfaces to remain wet for 10 minutes.
- Note – towelette, towel, wipe or cloth may be used interchangeably on product labeling
- Contains no (phosphates) (bleach) (phosphorous)
- REORDER CODE: USETWXX
- Patent Pending

### DIRECTIONS FOR USE

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

This product is **NOT** to be used for personal cleansing. This is **NOT** a baby wipe.

This product is effective against *Staphylococcus aureus*, *Salmonella enterica*, *Pseudomonas aeruginosa*, *Methicillin Resistant Staphylococcus aureus (MRSA)*, *Gentamicin Resistant Staphylococcus aureus (GRSA)*, *Herpes Simplex Type 1*, *Avian Influenza Virus*, and *Human Immunodeficiency Virus (HIV)*, and *Hepatitis B*

This product is 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 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

{For labels that list medical premises and metal 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 recommended for use on any hard, non-porous, (environmental) (household) surfaces such as counter tops, floors, walls, tables, bed frames, sinks, carts, cabinets, lights, etc.

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

- Open cap lid and pull up firmly to remove lid. Peel off inner foil seal, locate wipe in the center of the roll and insert corner of wipe through the opening in the lid. **DO NOT PUSH FINGER THROUGH OPENING.** Snap lid firmly back on. Always firmly snap lid shut to prevent wipes from drying out.
- For heavily soiled surfaces pre-clean (surfaces) using a clean, fresh towelette.
- Wipe surface to be disinfected with towelette.
- Use enough (TruKleen) wipes for surfaces to remain (visibly) (thoroughly) wet for 5 minutes (10 minutes for Adenovirus-5).
- (Then) (wipe) (dry) (clean) (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:**

- **Personal Protection:** When using (the TruKleen) disinfecting wipe, wear disposable protective equipment such as gloves, gowns, masks or eye coverings should be used.
- **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned surfaces can be disinfected with towelette. TruKleen Wipes can be used for this purpose.
- **Contact Time:** Use new towelette(s) on surface(s) and allow to remain (visibly) (thoroughly) wet for 5 minutes. (Then) (wipe) (dry) (clean) (or) let (surface(s) (air) dry)).
- **Disposal of Infectious Waste:** Dispose of soiled towelettes in accordance with Federal, State and local regulations for infectious waste disposal.

**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.
8. Wipe surface to be disinfected with towelette.
9. Allow surface(s) to remain wet (visibly) (thoroughly) wet for 10 minutes.
10. ((Then) (Wipe dry) (or) let (surface(s) (air) dry)).