

75512-1

7-25-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 25 2007

Ms. Heather Bjornson
Agent for Ebiox Limited
1150 18th Street, NW
Suite 1000
Washington, DC 20036

Subject: Ebiox TruKleen Wipes
EPA Registration No.: 75512-1
Notification Date: June 22, 2007
EPA Receipt Date: June 25, 2007

Dear Ms. Bjornson,

The following notification submitted in connection with registration under FIFRA section 3(c)9 and PR Notice 98-10.

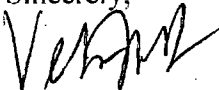
- Remove redundant use sites and parentheses

General Comments

Based on a review of the submitted materials, the notification is acceptable and apart of the records on file.

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

Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0080. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 75512-1	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ebiox TruKleen Wipes	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Ebiox Limited c/o Healthcare Enterprise House 17 Chesford Grange, Woolston, Warrington WA1 4RQ Cheshire, United Kingdom <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is to make minor text revisions per PR Notice 98-10 and is not subject to PRIA. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling of the Confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 25, 50, 75, 100, 200 wipes		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Consultant to Ebiox Limited	
4. Typed Name Heather R. Bjornson	5. Date June 22, 2007	

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WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Velma Noble
Antimicrobial Division
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

June 22, 2007

RE: Ebiox TruKleen™ Wipes – EPA Reg. No. 75512-1

Notification per PR Notice 98-10

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Velma:

Technology Sciences Group, on behalf of Ebiox Limited, is submitting the enclosed notification to make the following minor text revisions:

- To clarify and consistently state the public health pest as Human Immunodeficiency Virus Type 1 and HIV-1,
- To remove the repeated and redundant use sites listed in the Directions for Use section of the label, and
- Delete the parenthesis in paragraph 2, under the Directions for Use, and replace then with commas for easier reading.

You will find the following enclosed in support of this notification:

- 1) EPA notification application form,
- 2) One redline version of the revised label, and
- 3) Three clean copies of the revised label.

CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Please do not hesitate to contact me with any questions and/or concerns at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
Regulatory Consultant to Ebiox Limited.

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Ebiox TruKleen™ Wipes

Broad Spectrum, Fast Acting Disinfecting Wipes

Active Ingredients:

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

KEEP OUT OF REACH OF CHILDREN

WARNING

See back panel for additional precautionary statements

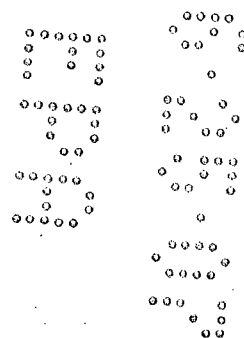
FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If on skin	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
<p>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.</p>	

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

Manufactured for:
Ebiox Ltd. (or Limited)
Healthcare Enterprise House
17 Chesford Grange
Warrington WA1 4RQ
U.K.

NOTIFICATION
Date Reviewed: 7/24/07
Reviewed By: *JM [Signature]*

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



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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

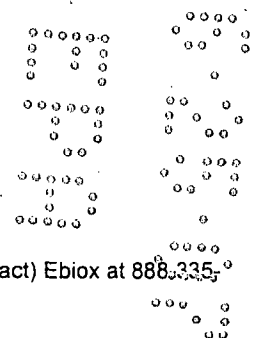
WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Avoid contact with skin. Wear protective eyewear such as goggles, face shield or safety glasses, protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking,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

Storage and Disposal

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

Storage and Disposal: Store in a 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.

- 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
- Bactericidal and Virucidal
- Can be used in critical care areas
- Prevents mold and mildew
- Multi-purpose, fast acting technology cleans, disinfects and eliminates odors in one easy step
- Kills 99.9% of broad spectrum bacteria, viruses, and fungi including: *Staphylococcus aureus* (Staph), *Salmonella enterica* (Salmonella), *Pseudomonas aeruginosa* (Pseudomonas) Methicillin Resistant *Staphylococcus aureus* (MRSA), *Herpes Simplex Type 1*, *Hepatitis B*, *Human Immunodeficiency Virus Type 1* (HIV-1), *Avian Influenza Virus H9N2*, and *Adenovirus 5*
- 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), *Herpes Simplex Type 1*, *Hepatitis B*, *Avian Influenza Virus H9N2*, and *Human Immunodeficiency Virus Type 1* (HIV-1)
- 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)
- 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



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- Effective against a wide range of microorganisms
- 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
- 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 H9N2*, *Human Immunodeficiency Virus Type 1 (HIV-1)*, 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 preclean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

This product is for use on any hard, non-porous, (environmental) (household) surfaces such as counter tops, floors, walls, tables, bed frames, sinks, carts, cabinets, lights, the outside of microwaves, refrigerators, stoves, trash cans, diaper pails, glazed tubs and tile, computers, phones, non-wooden patio furniture, etc.

Additional use sites include 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, bassinets, 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.

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

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. Follow disinfection directions.

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.

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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.

KILLS HIV -1 AND/OR HBV IN 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 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

- o **Personal Protection:** Clean-up should always be done wearing protective latex gloves, gowns, masks, and eye protection.
- o **Cleaning Procedure:** Blood and other body fluids containing HIV-1 must be thoroughly cleaned from surfaces and objects before application of this product.
- o **Contact Time:** Leave surface wet for 5 minutes. Use a 10 minute contact time for Adenovirus.
- o **Disposal of Infectious Waste:** Blood, body fluids, cleaning materials, and clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

