

75512-3

4-4-2007

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 4 2007

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

Subject: Ebiox TruKleen Spray
EPA Registration No.: 75112-2

Ebiox TruKleen Concentrate
EPA Registration No.: 75512-3

Notification Date: March 5, 2007
EPA Receipt Date: March 5, 2007

Dear Ms. Bjornson,

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

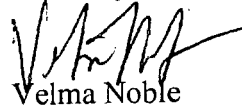
- Update the Company Address

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

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 75512-3	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ebiox TruKleen Concentrate	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 update the company address on the product label 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
Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container	<input checked="" type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1,2,4,8 oz, and 1 and 5 gallons		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued 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 or 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 March 5, 2007	

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Text in () is optional
Text in { } is administrative and will not appear on the labeling

NOTIFICATION
Date Reviewed: 9/21/07
Reviewed By: J. N. [Signature]

Ebiox TruKleen™ Concentrate

Broad Spectrum, Fast Acting Disinfecting Solution

Active Ingredients:

Alkyl dimethyl benzyl ammonium chloride (50% C ₁₂ , 30% C ₁₄ , 17% C ₁₆ , 3% C ₁₈).....	10.15%
Didecyl dimethyl benzyl ammonium chloride.....	9.16%
Poly (iminoimidocarbonyliminoimidocarbonyliminohexamethylene) Hydrochloride (PHMB).....	2.03%
Other Ingredients:	78.66%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See back panel for additional precautionary statements

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • If splashed in eyes, 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.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything to an unconscious person.
<p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p> <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.: 75512-3
EPA Est. No.: 9152-CA-1

Net Contents: (1 Gallon) (5 Gallons) (1 oz.) (2 oz.) (4 oz.) (8 oz.)

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

Ebiox Limited

Ebiox TruKleen™ Concentrate (EPA Reg. No. 75512-3)
Label version (8) redline dated March 5, 2007

Healthcare Enterprise House
17 Chesford Grange
Warrington WA1 4RQ
U.K.

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or safety glasses), protective clothing, and rubber gloves. Wear a respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N,R,P, or HE prefilter. 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

{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.

{Containers greater than 1 gallon}

Storage and Disposal

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

Pesticide Storage: Store in cool dry place and in original container in areas inaccessible to children and persons unfamiliar with its use.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal or excess pesticide, spray, or mixture of rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS

{For product in 5 gallon containers}

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.

- Multi-purpose, fast acting technology cleans, disinfects and eliminates odors in one easy step
- Bactericidal, Virucidal and Fungicidal
- Can be used in critical care areas
- Prevents mold and mildew
- Handles all daily clean-up jobs fast
- The smart way to clean and disinfect (Poultry Houses) (Farms)!
- 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

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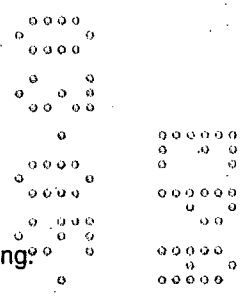
Staphylococcus aureus (MRSA), Herpes Simplex Virus Type 1, Hepatitis B, Human Immunodeficiency Virus (HIV), Human Coronavirus, Avian Influenza Virus, Adenovirus 5, and Trichophyton mentagrophytes (Athlete's Foot fungus)

- Handles all daily clean-up jobs fast
- Can be used in milk(ing) (stalls) (houses) (parlors)
- 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)
- For most household surfaces (all 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
- Cleans most household surfaces fast
- 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 effective against the following organisms: *Staphylococcus aureus (Staph)*, *Salmonella enterica (Salmonella)*, *Pseudomonas aeruginosa (Pseudomonas)*, *Methicillin Resistant Staphylococcus aureus*



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(MRSA), 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), barber and beauty salons, homes, farms, and poultry houses, 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 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, 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.

- For use on any hard, non-porous, environmental surfaces such as counter tops, floors, walls, tables, bed frames, plastic covered mattresses, sinks, carts, cabinets, lights, etc.
- 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.
- For use on 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, 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

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.

Fungicidal Activity: Ebiox TruKleen™ Concentrate is an effective fungicide against *T. mentagrophytes* (agent causes Athlete's Foot Fungus) at use solution of 2.6 oz per gallon of water in areas such as health spas, and shower and bath areas, health spas. Follow disinfection directions.

Mold and Mildew Control: At a use solution of 2.6 oz per gallon Ebiox TruKleen™ Concentrate 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.

For Combination Cleaning and Disinfecting inanimate, hard, non-porous surfaces:

- Dilute 2.6 ounces of Ebiox TruKleen™ Concentrate per gallon of water.
- For heavily soiled areas a pre-cleaning step is required.

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- Apply diluted solution (Ebiox TruKleen™ Concentrate) with a spray bottle, cloth, sponge, mop, by placing solution in a spray bottle.
 - Allow surfaces to remain (visibly) (thoroughly) wet for 5 minutes (10 minutes for Adenovirus).
 - ((Then) (Wipe dry) (or) let (surface(s) (air) dry)).
 - Prepare a fresh solution daily or, if necessary, more frequently if it becomes soiled or diluted.
 - For food contact surfaces such as counters and tables, rinse or wipe surface with potable water.
 - Do not use on utensils, glasses, dishes, or interior surfaces of appliances.

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

- **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 Waste:** Blood, body fluids, cleaning materials, and clothing must be autoclaved and disposed of according to 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 fresh water to just cover the intake valve. Add 2.6 ounce of this product (product name) for each gallon of fresh water added. 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 an 2.6 ounces of this product (product name) per gallon of water use-solution (or equivalent dilution) for at least 10 minutes. Rinse instruments thoroughly and dry before reuse. A fresh use-solution should be 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 Poultry House and Farm Premise Disinfection

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 transversed 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 2.6 oz per gallon of water for a period of 10 minutes.
6. Immerse 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.

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.

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2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or transversed 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 with 2.6 oz. per gallon of water for a period of 10 minutes.
6. Immerse 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.

Vehicle Disinfection

Treat all vehicles including mats, crates, cabs, and wheels. Apply use solution of 2.6 oz. per gallon of water with cloth, mop, sponge, brush, or mechanical sprayer thoroughly wetting surfaces. Allow to remain wet for 10 minutes. Wipe dry or let surfaces air dry.

REORDER CODE: USETCXX

