

62472-2

01/13/2011

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Mikah T. Reynolds
Alpha Tech Pet
119 Russell Street, Suite 21
Littleton, Massachusetts, 01460

JAN 13 2011

SUBJECT: KennelSol HC
EPA Registration Number: 62472-2
Application Dated: December 23, 2010
Receipt Date: December 14, 2010

Dear Mikah T. Reynolds:

This letter acknowledges receipt of the notification identified above submitted under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

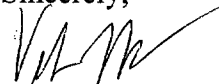
- To delete selected sites and reorganize label format.

Based on a review of the submitted information, this notification is acceptable. A copy has been inserted in your file for future reference.

General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.


Sincerely,



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

	United States Environmental Protection Agency Washington, DC 20460	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
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Application for Pesticide – Section I

1. Company/Product Number 62472-2	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) KennelSol HC	PM# 31	
5. Name And Address Of Applicant (Include ZIP Code) Alpha Tech Pet, Inc. 119 Russell Street, Suite 21 Littleton, Massachusetts 01460 <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.)

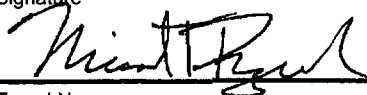
Submission of Label Notification to delete selected use sites and reorganize label format.

Please confirm receipt with Micah Reynolds: mreynolds@tsqusa.com, phone (202) 828-8967, or fax (202) 872-0745.

Section III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Packaging wgt. No. per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container	5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithographed <input type="checkbox"/> Other _____ <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled			

Section IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Micah T. Reynolds, Technology Sciences Group, Inc.	Title Regulatory Consultant	Telephone No. (Include Area Code) (202) 828-8967
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 Alpha Tech Pet, Inc.		
4. Typed Name Micah T. Reynolds		5. Date December 13, 2010



Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036
Direct: (202) 828-8967
Fax: (202) 872-0745
E-Mail: MReynolds@TSGUSA.com

Micah T. Reynolds
Regulatory Consultant

December 13, 2010

Alpha Tech Pet, Inc.
Label Notification to Delete use sites –
KennelSol HC, EPA Reg. No. 62472-2

Ms. Velma Noble, PM-31
Antimicrobials Division (7504P)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202

Dear Ms. Noble:

Technology Sciences Group, Inc., on behalf of Alpha Tech Pet, Inc., submits the enclosed label notification for the above referenced product. The enclosed proposed labeling for KennelSol HC removes uses that do not pertain to the registrant's intended markets for sale. All of the human uses sites, previously included and approved on former versions of this product are being removed to truncate and simplify the label and to be more in alignment with the registrant's other product, KennelSol (EPA Reg. No. 62472-1).

Please find enclosed the following documents supporting this Notification:

- 1) EPA Notification form (EPA Form 8570-1);
- 2) Redline version of the proposed label; and
- 3) Proposed Labeling for KennelSol HC – five copies.

If you have any questions or require additional information or clarification, please do not hesitate to contact me by phone at (202) 828-8967 or by e-mail at mreynolds@tsgusa.com.

Sincerely,

Regulatory Consultant to Alpha Tech Pet, Inc.

Enclosures

CC: S. Seitz (Alpha Tech Pet, Inc.)

***PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber or chemical resistant). Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes.

IF SWALLOWED: 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 do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer. If container size is 5 gallons or greater, the following Environmental Hazards statements will be used:)

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 Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp. 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.

KENNELSOL HC
EPA REG. NO. 62472-2
(REVISION 12/13/2010)

KENNELSOL HC

A multi-purpose germicidal detergent and deodorant effective in hard waters up to 400 ppm hard water (calculated as CaCO₃) plus 5 % organic serum. Disinfects, cleans, and deodorizes in one labor saving step.

For use in kennels, pet shops, tack shops, veterinary clinics, animal life science laboratories, breeding & grooming establishments, schools, colleges, equine farms, airports, hotels & motels. For use in households.

Active Ingredients:

Didecyl dimethyl ammonium chloride 10.14%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride 6.76%

Inert Ingredients: 83.10%

Total 100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER

See (right) (left) (side) (back) panel for Precautionary Statements and First Aid

EPA Reg. No. 62472-2

EPA Est. No. (insert Est. No. here)

NET CONTENTS (insert container size here)

Alpha Tech Pet, Inc.
119 Russell Street, Suite 21
Littleton, MA 01460

(Note to reviewer: Language in () is optional or interchangeable)

Bactericidal against the following pathogenic bacteria according to the AOAC Use-Dilution Test method, current edition, modified in the presence of 400 ppm synthetic hard water (calculated as CaCO₃) plus 5% organic serum:

- Pseudomonas aeruginosa¹
 - Staphylococcus aureus¹
 - Salmonella enterica
 - Acinetobacter calcoaceticus
 - Bordetella bronchiseptica
 - Chlamydia psittaci
 - Enterobacter aerogenes
 - Enterobacter cloacae
 - Enterococcus faecalis – Vancomycin Resistant (VRE)
 - Escherichia coli¹
 - Fusobacterium necrophorum
 - Klebsiella pneumoniae¹
 - Legionella pneumophila
 - Listeria monocytogenes
 - Pasteurella multocida
 - Proteus mirabilis
 - Proteus vulgaris
 - Salmonella enteritidis
 - Salmonella typhi
 - Salmonella typhimurium
 - Serratia marcescens
 - Shigella flexneri
 - Shigella sonnei
 - Staphylococcus aureus – Methicillin resistant (MRSA)
 - Staphylococcus aureus – Vancomycin Intermediate Resistant (VISA)
 - Staphylococcus epidermidis²
 - Streptococcus faecalis¹
 - Streptococcus pyogenes [cause of Scarlet fever]
- ¹ ATCC & antibiotic-resistant strain
² antibiotic-resistant strain only

Fungicidal against Aspergillus niger, Trichophyton mentagrophytes and Candida albicans according to the AOAC fungicidal test, modified in the presence of 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum.

Virucidal against *Canine parvovirus, Canine distemper, Feline leukemia, Feline panleukopenia, Feline picornavirus, **HIV-1 (AIDS virus), Influenza A/Hong Kong, Herpes simplex type 1, Herpes simplex type 2, Vaccinia, Rubella, Adenovirus type 4, Human coronavirus, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Rabies, Porcine parvovirus, Pseudorabies, Infectious bovine rhinotracheitis, Respiratory Syncytial Virus (RSV), Transmissible gastroenteritis virus (TGE), Infectious bronchitis (Avian IBV), Avian polyomavirus virus according to the virucidal qualification, modified in the presence of 400 ppm hard water (calculated as CaCO₃) plus 5 % organic serum.

DIRECTIONS FOR USE

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

DIRECTIONS FOR DISINFECTING: (Bactericidal, Fungicidal, Virucidal)

For use on hard, non-porous surfaces in animal care facilities such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, and plastic surfaces. Remove gross filth and heavy soil deposits then thoroughly wet surfaces. Use ½ ounces per gallon of water (2 ounces per gallon against canine parvovirus and Porcine parvovirus) for a minimum contact time of 10 minutes in a single application. Can be applied with a cloth, mop, or sponge, as well as by coarse spray or soaking. The use solution is prepared fresh for each use then discarded. Rinsing is not necessary unless floors are to be waxed or polished.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS:

Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, non-porous surfaces such as walls, floors, and table tops. Apply solution (½ ounces per gallon of water) with a cloth, mop, sponge or coarse spray making sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

VETERINARY CLINICS / ANIMAL CARE / ANIMAL LIFE SCIENCE LABORATORY / ZOOS / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENTS / EQUINE FARMS

DISINFECTION DIRECTIONS:

For cleaning and disinfecting hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a use-solution of ½ oz. of **KENNELSOL HC** per gallon of water (or equivalent dilution) (2 ounces per gallon of water against canine parvovirus or Porcine parvovirus), using a cloth, mop, sponge, spray, or soaking for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

For Heavy Duty Cleaning and / or Odor Control:

When greater cleaning is desired, use 1 - 2 oz. of KennelSol HC per gallon of water. Heavily soiled areas may require repeated cleaning before treatment.

***FOR CANINE PARVOVIRUS (AND PORCINE PARVOVIRUS) ACTIVITY:**

KennelSol HC is effective against canine parvovirus (and Porcine parvovirus) at 2 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

****KILLS HIV-1 (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C VIRUS) OF 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 / body fluids, and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1)(associated with AIDS) or Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OR HBV OR HCV ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

Personal Protection: Disposable protective gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood / body fluids and during decontamination procedures.

Cleaning Procedures: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (77°F) (room temperature). HBV and HCV are inactivated after a 10 minute contact time. Use a 10-minute contact time for all other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood / body fluids must be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument

**KENNELSOL HC
EPA REG. NO. 62472-2
(REVISION 12/13/2010)**

that (1) is introduced directly into the human body, either into or in 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.

(or)
This product is not for use on medical device surfaces.

(Note to reviewer: the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

(containers for household/residential use)

PESTICIDE STORAGE

Store in original container in areas inaccessible to children.

PESTICIDE DISPOSAL AND CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

(Note to reviewer: the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

(containers for commercial, industrial, and institutional use)

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

PESTICIDE STORAGE

Store in original container in areas inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

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

CONTAINER HANDLING

(For containers less than 5 gallons):

(Plastic containers:) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

(Note to reviewer: Language in () is optional or interchangeable)

Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling if available 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.

(For containers greater than 5 gallons):

(Plastic containers:) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available 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.