

62472-1

07/2/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUL 2 2009

Ms. Heather Bjornson
Agent for Alpha Tech Pet, Inc
789 Massachusetts Ave.
Lexington, MA 02420

Subject: Kennelsol
EPA Reg. No.: 62472-1
Amendment Date: January 30, 2009
EPA Receipt Date: February 4, 2009

Dear Ms. Bjornson,

The following amendment submitted in connection with registration under FIFRA section 3(c)9 is acceptable with conditions listed below.

Proposed Amendment

- Add additional organisms
- Revising basic and alternate formulations 1-3

Conditions

Revise the label as follows:

1. Revise the Environmental Hazards section on page 1 to be in agreement with the DDAC and ADBAC REDs by adding the following statement "*This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp.*"
2. Qualify porcelain under "Disinfecting" directions on page 2 as hard, nonporous by stating "*glazed*" porcelain.
3. The "Disposal of Infections Materials" statement under HIV directions on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling by deleting the term, should, and stating "*must.*"
4. The container rule no longer separates "Storage and Disposal" by container size; it is distinguished by use pattern such as residential, industrial, institutional, or commercial

Therefore, distinguish the first set of "Storage and Disposal" statements on page 2 as "containers"

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

for household/residential use and the second set as "containers for commercial, industrial, and institutional use."

General Comments

The Confidential Statements of Formula for the basic and alternate formulations 1-2 dated January 30, 2009 and #3 dated June 12, 2009 are acceptable. They are in compliance with PR Notice 91-2 and in agreement with the label.

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416 and Velma Noble (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

***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. 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
EPA REG. NO. 62472-1
(REVISION 1/30/2009)

KENNELSOL

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..... 2.535%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride 1.690%

Inert Ingredients:..... **95.775%**

Total **100.000%**

KEEP OUT OF REACH OF CHILDREN

DANGER

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

EPA Reg. No. 62472-1

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

NET CONTENTS *(insert container size here)*

Alpha Tech Pet, Inc.
789 Massachusetts Avenue
Lexington, MA 02420

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 2 2009

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

62472-1

(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 aeruginosa
- Proteus vulgaris
- Bordetella bronchiseptica
- Serratia marcescens
- Escherichia coli
- Staphylococcus aureus (antibiotic resistant)
- Fusobacterium necrophorum
- Klebsiella pneumoniae (antibiotic resistant)
- Streptococcus pyogenes
- Proteus mirabilis
- Salmonella enterica
- Salmonella typhimurium
- Escherichia coli (antibiotic resistant)
- Shigella sonnei
- Staphylococcus epidermidis (antibiotic resistant)
- Enterobacter cloacae
- Pasteurella multocida
- Pseudomonas aeruginosa (antibiotic resistant)
- Staphylococcus aureus
- Salmonella typhi
- Chlamydia psittaci
- Shigella flexneri
- Enterobacter aerogenes
- Streptococcus faecalis (antibiotic resistant)
- Klebsiella pneumoniae
- Streptococcus faecalis

Fungicidal against 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 at 1:64 dilution. (See side panel for additional information).

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, Rabies, Porcine parvovirus, Pseudorabies, Infectious bovine rhinotracheitis, Infectious bronchitis (Avian IBV), **Avian Influenza A (H3N2) virus (Avian Reassortant) (ATCC VR-2072), and **Avian Influenza A (H5N1) 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, porcelain, and plastic surfaces. Remove gross filth and heavy soil deposits then thoroughly wet surfaces. Use 2 ounces per gallon of water (8 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 (2 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 LABORATORIES / ZOOS / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENTS / EQUINE FARMS

DISINFECTION DIRECTIONS:

For disinfecting the following hard nonporous surfaces: equipment not 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. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a solution of 2 oz of KennelSol per gallon of water (or equivalent dilution) (8 ounces per gallon 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 CANINE PARVOVIRUS (AND PORCINE PARVOVIRUS) ACTIVITY:**

KennelSol is effective against Canine Parvovirus (and Porcine parvovirus) at 8 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

****SPECIAL INSTRUCTIONS FOR INACTIVATING AVIAN INFLUENZA:**

Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the disinfecting solution (2 oz per gallon of water) (660 ppm active quat) (equivalent use dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used in removing litter and manure. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

*****KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS**

in healthcare 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 surface/object 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) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection:

Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures:

Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time:

Effective against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate

amount of organic soil (5% blood serum) when used at a 1:64 dilution (providing 660 ppm of active quaternary) in 400 ppm CaCO₃ hard water for a contact time of 4 minutes at room temperature (20-250^C). Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses claimed (listed on labeling).

Disposal of Infectious Materials:

Blood and other body fluids ~~should~~ 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 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: If the container size is greater than one gallon, the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL (One Gallon or Less)

Store in original container in areas inaccessible to children. Do not reuse empty container. (Wrap and) Discard in trash or recycle.

(Note to reviewer: If the container size is greater than one gallon, the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL (Greater than One Gallon)

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 State Pesticide or Environmental Control

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

