

73232-1

1/28/2011

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

PRXIS Regulatory Consulting
c/o for Best Sanitizers
4110 136th Street, NW
Gig Harbor, WA 98332

JAN 28 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Attention: Ann Tillman
Regulatory Specialist

Subject: ALPET D2
EPA Reg. No. 73232-1
Amendment Letter Dated June 9, 2010

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided the following label revisions are incorporated:

- Under the section, **Fungicidal Activity**, add the following language after the sentence that ends "...on hard-nonporous surfaces": "Apply product with a sponge, cloth, or mechanical sprayer, or by total immersion. Treated surfaces must remain wet for 5 minutes".

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.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Zebora Johnson at (703) 308-7080.

Sincerely,

A handwritten signature in black ink that reads "M. Swindell".

Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Enclosures:

ALPET D2

READY TO USE
QUICK DRYING

**SURFACE SANITIZER FOR FOOD CONTACT AND NON-FOOD CONTACT SURFACES
DISINFECTANT - TUBERCULOCIDAL - VIRUCIDAL*
IDEAL FOR WATER SENSITIVE AREAS**

ACTIVE INGREDIENTS:

- Isopropyl Alcohol 58.6000 %
- Octyl Decyl Dimethyl Ammonium Chloride..... 0.0075 %
- Didecyl Dimethyl Ammonium Chloride..... 0.0045 %
- Dioctyl Dimethyl Ammonium Chloride 0.0030 %

OTHER INGREDIENTS: 41.3850 %
TOTAL..... 100.0000 %

[Depending on container size, the following statement may appear on the final label] - Not for individual sale

KEEP OUT OF REACH OF CHILDREN WARNING

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 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 530-432-7469/530-265-1800 between 8:30 A.M. and 4:30 P.M. Pacific Time for emergency medical treatment information.	

[Depending on container size, the following statements may appear on the final label] See side panel for first aid and precautionary statements. See accompanying pamphlet for directions for use and additional precautionary statements.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear, such as safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Physical or Chemical Hazards

Flammable: Keep away from heat and open flame.

Manufactured For:
BEST SANITIZERS, INC.
 P.O. BOX 1360
 PENN VALLEY, CA
 95946

EPA Reg. No. 73232-1
EPA Est. No. 550-KY-001

Net Contents:

Batch No.

ACCEPTED
with COMMENTS
EPA Letter Dated:
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Under the Federal Insecticide,
 Fungicide, and Rodenticide Act as
 amended for the pesticide,
 registered under EPA Reg. No. **73232-1**

[Note to Reviewer: For containers of 5 gallons or more, the following Environmental Hazards language will appear on the final product label]

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.

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 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 medical devices prior to sterilization or high level disinfection.

DISINFECTION

For disinfection of inanimate, precleaned, hard, non-porous surfaces such as chairs, countertops, drawer pulls, carts, baskets, tables, cabinets, telephones, plastic surfaces, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces, rubber gloves and boots, and other related hard surfaces in hospitals, operating rooms, medical clinics, nursing homes, laboratories, schools, day care centers, funeral homes.

TO DISINFECT: Completely preclean surfaces to be disinfected. This product may be used for this purpose. Then, apply with a sponge, cloth, or mechanical sprayer, or by total immersion. When applied with a mechanical spray, spray should be coarse. Surfaces must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 5 minutes. This product is an effective disinfectant according to the AOAC Use Dilution Test method on hard inanimate surfaces against: *Staphylococcus aureus* MRSA (ATCC 33591), *Staphylococcus aureus* (ATCC 6538), *Enterococcus faecium* VRE (ATCC 51559), *Escherichia coli* O157:H7 (ATCC 43895), *Pseudomonas aeruginosa* (ATCC 15442), *Listeria monocytogenes* (ATCC 19111), and *Salmonella choleraesuis* (ATCC 10708).

Respiratory illnesses attributable to Pandemic H1N1 are caused by influenza A virus. Alpet D2 is a broad-spectrum hard surface disinfectant that has been shown to be effective against Avian influenza H9N2 and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu). Treated surfaces must remain wet for 5 minutes.

FUNGICIDAL ACTIVITY - This product is an effective against the fungus *Trichophyton mentagrophytes* (ATCC 9533) on hard non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes.

TUBERCULOCIDAL ACTIVITY - This product exhibits disinfectant efficacy against *Mycobacterium bovis* (BCG) in 5 minutes at 20°C when used as directed on previously cleaned hard nonporous inanimate surfaces.

***KILLS HIV-1 AND HBV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS**

PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (e.g. hospitals, nursing homes) 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) (associated with AIDS) or Hepatitis B Virus (HBV).

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

Personal Protection: Wear disposable latex gloves, protective gown, face mask and eye covering, as appropriate, when handling items soiled with blood or body fluids.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.

Contact Time: Leave surfaces wet for five minutes. For other organisms identified above allow surface to remain wet for 5 minutes)

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73232-1

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.

SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD FOOD CONTACT NONPOROUS SURFACES IN FOOD CONTACT LOCATIONS:

For sanitizing food processing equipment, dairy equipment, food utensils, dishes, silverware, glasses, sink tops, countertops, refrigerated storage and display equipment and other hard nonporous, food contact surfaces. Wash and rinse all articles thoroughly, then apply this product. If the article cannot be washed and rinsed, clean thoroughly in an appropriate fashion, then apply this product. Apply with a sponge, cloth, or mechanical sprayer, or by total immersion. When applied with a mechanical spray, spray should be coarse. Surfaces must be sprayed until thoroughly wetted. Treated surfaces must remain wet for 1 minute.

Apply to sink tops, countertops, refrigerated storage and display equipment and other stationary hard surfaces by sponge, cloth, brush or coarse spray. Surfaces should remain wet for at least one minute followed by adequate draining and air-drying. Use fresh solution in all applications. Dishes, silverware, glasses, cooking utensils and other similar size food processing equipment can be sanitized by immersion in this product.

This product is an effective sanitizer against *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* (ATCC 11299), *Escherichia coli* O157:H7 (ATCC 43895), *Pseudomonas aeruginosa* (ATCC 15442), *Salmonella typhimurium* (ATCC 13311), *Listeria monocytogenes* (ATCC 19111), *Enterobacter sakazakii* (ATCC 51329), and *Vibrio cholerae* (ATCC 14035) on hard non-porous environmental surfaces. Treated surfaces must remain wet for 60 seconds. Allow to air dry.

~~This product is an effective against the fungus *Trichophyton mentagrophytes* (ATCC 9533) on hard non-porous environmental surfaces. Treated surfaces must remain wet for 5 minutes.~~

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE-Open dumping is prohibited. Store only in the original container. Keep this product under locked storage sufficient to make it inaccessible to children or people unfamiliar with its proper use. Store in a cool dry area away from flames, sparks or other sources of heat or ignition. If ignited, use dry chemical or CO₂ extinguisher. If a large quantity is spilled, dilute with water and mop or wipe dry.

PESTICIDE DISPOSAL-Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL- Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. if available (Nonrefillable ≤ 5 gallons): Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

(Nonrefillable > 5 gallons): Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it 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 onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

LIMITED WARRANTY AND DISCLAIMER

NOTICE: Best Sanitizers, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the Directions For Use. Buyer assumes all risks of use and handling which is a variance in any way with the directions herein. Best Sanitizers, Inc. makes no other express or implied warranty of fitness or merchantability. In no case shall Best Sanitizers, Inc. or the seller be liable for consequential, special or indirect damages resulting from the use or handling of this product. Best Sanitizers, Inc. and Seller offer this product and the Buyer and user accept it, subject to the foregoing **Limited Warranty and Disclaimer** which may be varied only by agreement in writing signed by a duly authorized representative of Best Sanitizers, Inc.

ACCEPTED
with COMMENTS
EPA Letter Dated:

Rev. Jan. 6, 2011

JAN 28 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 73232