

73232-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

11/23/2005

1/6

NOV 23 2005

Best Sanitizers, Inc.  
c/o Pyxis Regulatory Consulting  
4110 136<sup>th</sup> Street, N. W.  
Gig Harbor, WA 98332

Attention: Michael Kellogg

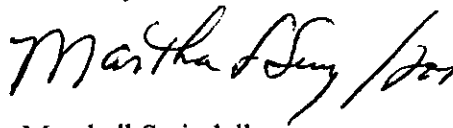
Subject: Alpet D2  
EPA Registration No. 73232-1  
Your Notification Dated October 25, 2005

This will acknowledge receipt of your notification to package the product in a different container size (5-gallon) and to include an "Environmental Hazards section to the label, submitted under the provisions of FIFRA Section 3(c)(9). Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and PR Notice 93-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely



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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

PYXIS REGULATORY CONSULTING, INC.

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

2/6  
Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

October 25, 2005

COURIER DELIVERY

Marshall Swindell (PM33)  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 Bell Street  
Arlington, VA 22202

RE: Best Sanitizers, Inc. – Alpet D2 (EPA Reg. No. 73232-1)  
Submission of Label Notification per PR Notices 93-10 and 98-10

Dear Mr. Swindell,

On behalf of Best Sanitizers, Inc. please find the enclosed label notification for Best Sanitizers, Inc.'s Alpet D2 (EPA Reg. No. 73232-1) product. Best Sanitizers, Inc. is proposing to package Alpet D2 in 5-gallon containers and as such is adding effluent discharge labeling statements per PR Notice 93-10.

In support of this submission, please find the following:

1. Application for Registration (EPA Form 8570-1)
2. One (1) copy of the Alpet D2 label with tracked changes [Editor's Note: Added text is underlined]
3. One (1) copy of the Alpet D2 label with changes incorporated
4. Letter of Authorization from Best Sanitizers, Inc.

Please feel free to call me if you have any questions or need any additional information.

Best Regards,

  
Michael Kellogg

Enclosures

cc: Duncan Badertscher; Best Sanitizers, Inc.



United States  
Environmental Protection Agency  
Washington, DC 20460

 Registration  
 Amendment  
 Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 73232-1	2. EPA Product Manager M. Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Best Sanitizers, Inc./ ALPET D2	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Best Sanitizers, Inc. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <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 per PR Notices 93-10 and 98-10. 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 or 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:

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	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Notification must be submitted		If "Yes" Unit Packaging wgt.      No. per container	If "Yes" Package wgt      No. per container

3. Location of Net Contents Information  
 Label  Container

4. Size(s) Retail Container  
2 oz, 4 oz, 32 oz, 1, 5, 55 gallons

5. Location of Label/Directions  
 On Label  
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product  
 Lithograph Paper glued Stenciled  Other \_\_\_\_\_

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Michael Kellogg	Title Agent	Telephone No. (Include Area Code) (253) 353-7369
-------------------------	----------------	---

**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.

2. Signature 	3. Title Agent	6. Date Application Received (Stamped)
4. Typed Name Michael Kellogg	5. Date 10/25/05	

4/6

# 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 %
Diocetyl Dimethyl Ammonium Chloride .....	0.0030 %
<b>OTHER INGREDIENTS:</b> .....	<b>41.3850 %</b>
<b>TOTAL</b> .....	<b>100.0000 %</b>

[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"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
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 530-432-7460 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

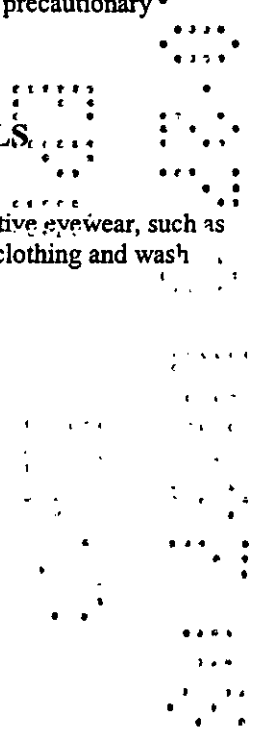
Flammable: Keep away from heat and open flame.

**Manufactured For:**  
**BEST SANITIZERS, INC.**  
**P.O. BOX 707**  
**PENN VALLEY, CA**  
**95946**

**E.P.A. Reg. No. 73232-1**  
**E.P.A. Est. No. 550-KY-001**

Net Contents:

Batch No.



[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 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). This product is also effective against the Norwalk Virus.

**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)
- 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.

6/10

**SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD 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 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.

**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. Do not reuse empty 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 CO<sub>2</sub> 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**-(Larger than 1gallon)- Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary land fill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. (1 gallon and smaller)- Do not reuse empty container. Wrap container and put in trash.

**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.