

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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MAR 2 4 2010

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

Subject: Alpet D2

EPA Registration Number 73232-1

Your Notification Dated February 24<sup>th</sup>, 2010 EPA Received Date February 26<sup>th</sup>, 2010

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to revise the container disposal language as per PR Notice 2007-4, is acceptable.

The notification has been made part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)

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Please read instructions on reverse perore completing	g form.	Form A	pproved	. OMB No.	2070-0060	. Approval expires 2-28-95
Environmental	ted States Protection Ag ton, DC 20460	ency	✓	Registra Amenda Other		OPP Identifier Number
A	pplication for	Pesticide - Se	ction	1		
1. Company/Product Number 73232-1		2. EPA Product Me M. Swindell	anager		1 1 .1	posed Classification None Restricted
4. Company/Product (Name) Best Sanitizers, Inc./ ALPET D2		PM#	33			TO T
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	))		t is sim	ilar or ident	ical in con	FIFRA Section 3(c)(3) nposition and labeling
		ction - II				
Amendment - Explain below.  Recubmission in response to Agency letter de Notification - Explain below.		ſ 1	etter dat * Applica	ation.	e to	
Explanation: Use additional page(s) if necessery.  Notification of label change per PR Notice 2007-4. Thi regulations at 40 CFR 156.10, 156.140, 156.144, 156.  Formula for this product. I understand that it is a violat amended label is not consistent with the requirements and I may be subject to enforcement action and penalt	s notification is consi 146, and 156.156. N ion of 18 U.S.C. Sec of 40 CFR 156.10, 19 ies under sections 12	stent with the guidance to other changes have be 1001 to willfully make 56.140, 156.144, 156.14 and 14 of FIFRA.	een mad any false	de to the label statement to	ing or the C EPA. I furt	onfidential Statement of her understand that if the
	Se	ction - III				
1. Material This Product Will Be Packaged In:						
Child-Resistant Packaging  Yes  No  * Certification must be submitted  Unit Packaging  Yes  V No  If "Yes" Unit Packaging wgt.	No. per If "Y	or Soluble Packeging Yes No es" No. per age wgt		2. Type of	Container  Metal Plastic Glass Paper Other (Sp	pecify)
3. Location of Net Contents Information 4	. Size(s) Retail Cont	einer	5. Lo	cation of Lab	el Direction	18
✓ Label Container		5 gal, 55 gal	[ ]	On Label	accompanyin	
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled					
		tion - IV				
1. Contact Point (Complete items directly below for	identification of ind	vidual to be contacted	d, if nec	essery, to pr	ocess this e	application.)
Name Ann M. Tillman	Title Agent				(253) 85	No. (Include Area Code)
I certify that the statements I have made on th I acknowledge that any knowlingly felse or mi both under applicable law.					npletë. 🕴	6. Date Application Received  (Stamped)
2. Signature July Millima	3. Title Agent					c ccce
4. Typed Name Ann M. Tillman	5. Date	2/24/	2010	<i>y</i>		,

#### PYXIS REGULATORY CONSULTING, INC.

4110 136th St. NW Gig Harbor, WA 98332

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

February 24, 2010

#### COURIER DELIVERY

**COURIER DELIVERY** Marshall Swindell (PM33) Document Processing Desk (NOTIF) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency Room S-4900, One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202-4501

Dear Mr. Swindell,

Best Sanitizers, Inc. – Alpet D2 (EPA Reg. No. 73232-1) RE: Revision to Container Disposal Instructions per PRN 2007-4

On behalf of Best Sanitizers, Inc. please find the enclosed label notification revising the container disposal instructions per PRN 2007-4 for Alpet D2 (EPA Reg. No. 73232-1).

In support of this notification submission, we submit the following documents:

- 1. Completed Application for Registration (EPA Form 8570-1)
- 2. One (1) copy of the Alpet D2 (EPA Reg. No. 73232-1) labeling with changes tracked
- 3. One (1) copy of the Alpet D2 (EPA Reg. No. 73232-1) labeling with changes incorporated
- 4. Letter of Authorization

Please feel free to contact me by phone (253) 853-7369 or by email at Ann@PyxisRC.com if you have any questions or need any additional information.

Sincerely,

Ann M. Tillman

**Enclosures** 

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#### 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> <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
treatment. Y	duct container or label with you when calling a poison control center or doctor, or going for ou may also contact 530-432-7460 between 8:30 A.M. and 4:30 P.M. Pacific Time for emergency ment 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

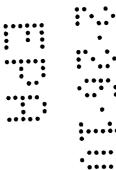
Flammable: Keep away from heat and open flame.

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 ADAINST 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.



### 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. 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-** Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. if available (Nonrefillable  $\leq 5$  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  $\frac{1}{4}$  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 1/4 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 handing 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.

Rev. 1/26/2010

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