

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

December 1, 2016

Tony Herber Agent Best Sanitizers, Inc. PO Box 1360 Penn Valley, CA 95946

Subject: PRIA Label Amendment – Adding public health organisms and efficacy claims; reduced contact time for nonfood contact sanitization Product Name: Alpet D2 EPA Registration Number: 73232-1 Application Date: 7/15/16 Decision Number: 519787

Dear Mr. Herber:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at <u>heffernan.aline@epa.gov</u>.

Sincerely,

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Julie Chao, Product Manager 33 Regulatory Management Branch 1 Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure: Accepted Label

[Bracketed text] is optional; text in {braces} is informational to the reviewer.

## ALPET D2

#### READY TO USE FAST ACTING<sup>1</sup>

Kills 99.9% of bacteria on non-food contact surfaces [in 10 seconds] Kills 99.999% of bacteria on food contact surfaces [in 60 seconds] Sanitizes food contact surfaces in 60 seconds Sanitizes non-food contact surfaces in 10 seconds Kills 99.9% of bacteria in 10 seconds<sup>1</sup> Kills 99.999% of bacteria in 60 seconds<sup>2</sup> QUICK DRYING HIGHLY EVAPORATIVE NO-RINSE

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

ACTIVE INGREDIENTS:	
Isopropyl Alcohol	
Octyl Decyl Dimethyl Ammonium Chloride	
Didecyl Dimethyl Ammonium Chloride	
Dioctyl Dimethyl Ammonium Chloride	
OTHER INGREDIENTS:	
TOTAL	

**ACCEPTED** Dec 01, 2016

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 73232-1

[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	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. For no	on-emergency product information, contact 1-888-225-3267 between 8:00 A.M. and 4:30 P.M.
Pacific Time. For	24/7 emergency response regarding this product, contact CHEMTREC at 1-800-424-9300

[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 and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

<sup>&</sup>lt;sup>1</sup> Non-food Contact Surfaces

<sup>&</sup>lt;sup>2</sup> Food Contact Surfaces

### **Physical or Chemical Hazards**

Flammable: Keep away from heat and open flame.

Manufactured [For:] By: BEST SANITIZERS, INC. P.O. BOX 1360 PENN VALLEY, CA 95946 E.P.A. Reg. No. 73232-1 E.P.A. Est. No. 073232-KY-001

Net Contents: Lot No. (Expiry Date)

[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 you 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.

### CLEANING

Alpet D2 [This product] is recommended for use as a cleaner on hard non-porous food contact and non-food contact surfaces such as [conveyors, belts, driers, blanchers, roasters, ovens, refrigerators, freezers, chillers, hoppers, extruders, fillers, fill heads, mixers, blenders, meat slicers, saws, snippers, choppers, dicers, grinders, huskers, peelers, presses, evaporators, pasteurizers, graders, sizing cups, labelers, packaging equipment, case packers, pipelines, bins, crates, containers, tubs, totes, carts, buggies, tanks, vats, walls, floors, doors, door handles, tables, counters tops, benches, chairs, drip pans, troughs, drains, racks, forklifts, tires, pallet jacks, pallets, timeclocks, hand hygiene dispensers, hard hats, aprons, gloves, boots, tools, tool boxes, knives, utensils, thermometers, control panels, proximity switches, thermostats, motors, pumps and scales]. Remove gross food particles and soil from the surface. Apply this product [Alpet D2] without dilution to the surface and wipe clean. Allow to dry. A water rinse after applying the product is permissible in wet environments if necessary to aid in the cleaning process.

### SANITIZING NON-FOOD CONTACT SURFACES

This product [Alpet D2] is recommended as a sanitizer for use on non-food contact surfaces such as [conveyors, floors, walls, tables, chairs, benches, cabinets, troughs, carts, baskets, forklifts, tires, pallet jacks, plastic pallets, telephones, plastic surfaces, glazed ceramic, glazed porcelain, chrome, stainless steel, aluminum, laminated surfaces] and other related hard, non-porous surfaces. Preclean surfaces prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe, sponge, or by total immersion and ensure exposure to sanitizer for at least 10 seconds. Allow surfaces to air dry. This product [Alpet D2] is effective against *Staphylococcus aureus* [(ATCC 6538)] and *Klebsiella pneumoniae* [(ATCC 4352)].

### FOOTWEAR SANITIZER

This product [Alpet D2] is recommended as a sanitizer for use on outside surfaces of non-porous waterproof footwear such as boots, and work boots. Preclean footwear prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 10 seconds. Allow surfaces to air dry.

# SANITIZING OF FOOD PROCESSING EQUIPMENT AND OTHER HARD NON-POROUS FOOD CONTACT SURFACES:

This product is recommended for use as a sanitizer on 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.

Preclean surfaces prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe, sponge, or by total immersion. Surfaces must be thoroughly wetted. Treated surfaces must remain wet for 60 seconds [1 minute].

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

Alpet D2 [This product][kills 99.999% of the following bacteria:] [is an effective sanitizer against] *Staphylococcus aureus* [(ATCC 6538)], *Escherichia coli* [(ATCC 11299)], *Escherichia coli* 0157:H7 [(ATCC 43895)], *Pseudomonas aeruginosa* [(ATCC 15442)], *Salmonella enterica* (formerly *typhimurium*) [(ATCC 13311)], *Listeria monocytogenes* (ATCC 19111), *Enterobacter sakazakii* [(ATCC 51329)], *Klebsiella pneumoniae* [(ATCC 4352)] and *Vibrio cholerae* [(ATCC 14035)]- on hard non-porous food contact surfaces. Treated surfaces must remain wet for 60 seconds [1 minute]. Allow to air dry.

### SANITIZING NON-POROUS WATERPROOF GLOVES

This product [Alpet D2] is recommended as a sanitizer for use on non-porous and waterproof gloves. Preclean gloves prior to sanitizing. This product may be used to preclean. To sanitize, apply by spray, wipe or total immersion to ensure exposure to sanitizer for at least 60 [1 minute] seconds. Allow surfaces to air dry. Do not rinse.

### Wisconsin State Board of Health Directions for Eating Establishments

1. Scrape and pre-wash utensils and glasses whenever possible. 2. Wash with a good detergent or compatible cleaner. 3. Rinse with potable water. 4. Sanitize in an undiluted solution of this product. Immerse all utensils for at least two minutes or for contact time specified by governing sanitary code. 5. Place sanitized utensils on a rack or drain board to air-dry. 6. Prepare a fresh sanitizing solution at least daily or when visibly soiled or diluted. NOTE: A clean potable water rinse following sanitization is not permitted under HFS 196, Ref. Appendix 7-204.11 of the Wisconsin Administrative Code.

### DISINFECTION

This product is recommended for use as a disinfectant on 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.

Preclean surfaces prior to disinfecting. This product may be used to preclean. To disinfect, apply with a sponge, wipe, 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.

### [Bacteria:]

This product [kills 99.9% of the following bacteria] {-or-}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* and *Salmonella enterica* (formerly choleraesuis) [ATCC 10708)].

### [Viruses:]

This product [Alpet D2] is an effective virucidal disinfectant against the following viruses on hard non-porous surfaces: Norovirus (Feline Calicivirus as surrogate) [(ATCC VR-782)], Influenza A H1N1 [(ATCC/IRR FR-371)], Hepatitis B Virus, and Human Immunodeficiency Virus Type 1 (HIV-1)

### [Fungi]

This product [Alpet D2 is an effective fungicidal disinfectant against [the fungus] *Trichophyton mentagrophytes* [(ATTC 9533)] on hard non-porous environmental surfaces. [Apply product with a sponge, wipe, or mechanical sprayer, or by total immersion. 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 non-porous 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.

{The following statement will appear on container labels only if healthcare use sites are listed on the label}

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. Alpet D2 [This product] may be used to clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

### 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  $CO_2$  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. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or by other procedures allowed by state and local regulations.

### 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. To the extent consistent with applicable law, Best Sanitizers, Inc. makes no other express or implied warranty of fitness or merchantability. To the extent consistent with applicable law, 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.





and [Kosher symbol]

{For labels greater than one quart} [UN1219 ISOPROPANOL, 3, PG II FLAMMABLE LIQUID Hazard Rating NFPA: (2) Health/ (3) Fire/ (0) Instability]