

#### U.S. ENVIRONMENTAL PROTECTION **AGENCY**

Office of Pesticide Programs Antimicrobials Division (7510C) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

NOTICE	OF	<b>PESTICID</b>	E

Reregistration

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	 Registration	

ì	Li Artog.	Date of Issuance.		
	Number:			
	73232-3	MAY	2 3	2011
	Term of Issuance:		,	

Name of Pesticide Product: Smart-

San™ D2

Name and Address of Registrant (include ZIP Code):

Best Sanitizers, Inc. P. O. Box 1360 Penn Valley, CA 95946

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
- 2. Make the labeling changes listed below before you release the product for shipment:
  - a. Add the phrase "EPA Registration Number 73232-3."

Signature of Approving Official:

Marshall Swindell

**Product Manager-33** 

Regulatory Management Branch I Antimicrobials Division (7510P)

Date:

MAY 2 3 2011

- 3. The Confidential Statement of Formula dated January 28<sup>th</sup>, 2011, is acceptable.
- 4. Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Marshall Swindell

Product Manager 33 Regulatory Branch I

Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling)

3085

#### Smart-San<sup>TM</sup> D2

READY TO USE OUICK DRYING

### DISINFECTANT – TUBERCULOCIDAL - VIRUCIDAL\* IDEAL FOR WATER SENSITIVE AREAS

#### **ACTIVE INGREDIENTS:**

Isopropyl Alcohol	58.6000 %
Octyl Decyl Dimethyl Ammonium Chloride	
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> </ul>
	<ul> <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 530-265-1800 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 1360 PENN VALLEY, CA 95946

ACCEPTED with COMMENTS EPA Letter Dated:
MAY 2 3 2011

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

Under the Federal Insecticide, Net Contents: Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 73232-3

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, rubber gloves and boots, and other related hard surfaces in hospitals, operating rooms, medical clinics, nursing homes, laboratories, schools, day care centers, funeral homes, physician offices, dental clinics, veterinary clinics and any other facility where the prevention of cross contamination is important.

TO DISINFECT: Completely preclean surfaces to be disinfected. This product may be used for this purpose. Apply product with a mechanical sprayer. Surfaces must be sprayed until thoroughly wet. Treated surfaces must remain wet for 1.5 minutes. This product is an effective disinfectant according to the AOAC Germicidal Spray 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 Norovirus and treated surfaces must remain wet for 2 minutes.

**TUBERCULOCIDAL ACTIVITY** – This product exhibits disinfectant efficacy against *Mycobacterium bovis* (BCG) in 2 minutes at 20°C according to the AOAC Germicidal Spray Test method 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 FILLIDS

**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 two minutes.

Disposal of Infectious Materials: Blood and other body fluids should be audiclaved and disposed of according to federal, state and local regulations for infectious was a EPA Letter Dated:

MAY 23 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 73232-3

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#### 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 ≤ 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.

[EPA approval date]

ACCEPTED with COMMENTS EPA Letter Dated:

MAY 2 3 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 7323233