

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE: <u> X </u> Registration <u> </u> Reregistration (under FIFRA, as amended)</p>	EPA Reg. Number: 70299-7	Date of Issuance: DEC 15 2005
	Term of Issuance: Conditional	
	Name of Pesticide Product: Sanidate	
Name and Address of Registrant (include ZIP Code): BioSafe Systems 80 Commerce Street Glastonbury, CT 06033		
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.		
<p>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.</p> <p>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.</p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</p> <ol style="list-style-type: none">1. Submit and/or cite all data required for registration/ reregistration 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 reregistration of your product under FIFRA section 4.2. Make the following label changes:<ol style="list-style-type: none">a. Revise the EPA Registration Number to read, "EPA Reg. No. "70299-7".		
Signature of Approving Official: Marshall Swindell, PM 33 Regulatory Management Branch 1 Antimicrobial Division (7510C)		Date: DEC 15 2005

288

Page 2

EPA Registration No. 70299-7

3. The submitted Confidential Statements of Formulas dated September 22, 2005, for the Basic formulation is in compliance with PR Notice 91-2, agrees with the label and is acceptable. However, you must resubmit study results as noted in Findings #4 and #7 in the attached copy of the Product Chemistry Review. These two studies must be submitted within six (6) months of the date of the Registration Notice.

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.

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

Antimicrobial Division (7510C)

Enclosure

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SANIDATE

For the disinfection of hard, non-porous surfaces, structures and equipment.

FOR COMMERCIAL USE ONLY

ACTIVE INGREDIENT:

Hydrogen Peroxide27.0%

Peroxyacetic Acid2.0%

OTHER INGREDIENTS:71.0%

TOTAL:100.0%

ACCEPTED
with COMMENTS
EPA Letter Dated:
DEC 15 2005
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
70299-7

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand this label, find someone to explain it to you in detail.)

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.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by the poison control center. • Do not give anything by mouth to an unconscious person.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

Sold by: BioSafe Systems, 36 Commerce Street, Glastonbury, CT 06033

EPA Registration No.: (pending as File Symbol 70299-T)

EPA Establishment No.: XXXXX-XX-XXX

Net Contents: XX

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMAN AND DOMESTIC ANIMALS**

CORROSIVE: Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating and drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. When spraying or fogging, wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and National Institute for Occupational Safety and Health.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either indirectly or through drift.

SANIDATE works best when diluted with water with minimal levels of organic or inorganic materials, and with water having a neutral pH. Thoroughly rinse out tank with water before mixing concentrate. SANIDATE will readily mix with clean, neutral water and does not require agitation.

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SANIDATE concentrate should not be combined or mixed with any other pesticide.

DEC 15 2005

APPLICATION DIRECTIONS:

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

GENERAL DISINFECTION

SANIDATE disinfects as it cleans in one operation. SANIDATE can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, tile, and use sites listed on this label made of linoleum, vinyl, porcelain, plastic polyethylene, stainless steel, or glass.

70299-7

SURFACE DISINFECTION

SANIDATE is an effective disinfectant against gram positive and negative bacteria (vegetative forms) such as *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *E. coli* and may be used in general commercial environments to clean, disinfect and deodorize inanimate surfaces, such as:

- Floors, walls, and other non-porous surfaces such as tables, chair counter tops, garbage cans/bins, bathroom fixtures, sinks, bed frame shelves, racks, carts, refrigerators, coolers, tile, use sites listed on this label made of linoleum, vinyl, porcelain, plastic (such as polyethylene), stainless steel, or glass
- Schools, colleges, industrial facilities, dietary areas, office building recreational facilities, retail and wholesale establishment.
- Animal hospitals, veterinary clinics, animal life science laboratories, kennels, kennel runs, cages, feeding and watering equipment, pet shops, zoos, pet animal quarters, poultry premises, trucks, hatcheries and live stock quarters.

Prepare SANIDATE disinfecting solution by adding 2.5 fl. oz. of the product to 1 gallon of potable water. Remove gross filth from surfaces to be disinfected by cleaning with SANIDATE solution by wiping, mopping, or as a coarse spray. Applications involving

SANIDATE; (pending as File Symbol 70299-T)
MASTER LABEL - Label version (5) dated March 30, 2005

treatment of food contact surfaces, require a sterile or potable water rinse following disinfection.

COMBINATION DISINFECTION AND CLEANING

SANIDATE is effective against *Salmonella enteritidis*, *Salmonella typhimurium*, *Proteus vulgaris*, *Streptococcus pyogenes*, *Enterobacter aerogenes*, *Lactobacillus malefermentans*, *Pediococcus damnosus*, *Listeria monocytogenes*, *Klebsiella pneumoniae* and *Escherichia coli*. Use a rate of 1.3 fl. oz per gallon for hard non-porous surfaces that are lightly soiled or have been pre-rinsed to remove gross contamination. For heavily soiled hard non-porous surfaces use a rate of 2.6 oz per 1 gallon of water. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

For treating sewer backups and for flooding remediation, prepare disinfecting solution of **SANIDATE** by adding 2.5 fl. oz. of the product to 1 gallon of potable water. Remove gross filth from surfaces by cleaning with **SANIDATE** solution by wiping, mopping, or as a coarse spray. Applications involving treatment of food contact surfaces, require a sterile or potable water rinse following cleaning.

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

SANIDATE is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities. This product is effective at 1.3 fl. oz. per 1 gallon water for pre-washed or lightly soiled surfaces to disinfect. For heavily soiled or surfaces that have not been pre-cleaned use a rate of 2.6 oz per gallon. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

SANIDATE is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, **SANIDATE** is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operation tables, kennel runs, cages and feeding and watering equipment. In addition **SANIDATE** will disinfect bins and cans, and any other areas that are prone to odors caused by microorganisms.

All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS, AND CRATES

1. Remove all poultry and feeds from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.

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Letter Dated:

DEC 15 2005

Under the Federal Insecticide,
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70299-7

5. Saturate all surfaces with a solution of 1.3 fl. oz. per 1 gallon of water for a period of 10 minutes.
6. Immerse all types of equipment used in handling and restraining poultry, as well as forks, shovels and scapers used for removing litter and manure.
7. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

POULTRY HATCHERY DISINFECTION

1. Clean out any remaining eggs and chicks. Remove all poultry and feeds from premises, trucks, coops and crates
2. Remove gross soils, such as litter, droppings, down shell fragments or other hatching related debris from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances and equipment.
4. Thoroughly clean all surfaces with soap or detergent and rinse thoroughly with water.
5. Saturate all surfaces with a solution of 1.3 fl. oz. per 1 gallon of water for period of 10 minutes.
6. Ventilate buildings, coops, and other closed spaces. Allow to dry before reintroducing eggs or poultry.
7. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, KENNELS, HUTCHES)

1. Remove all animals and feed from premises, vehicles and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with a solution of 1.3 fl. oz. per 1 gallon of water for period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scapers used for removing litter and manure.
7. Ventilate buildings, cars, boats and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set or dried.
8. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent, and rinse with potable water before reuse.

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DEC 15 2005

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DISINFECTION OF NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For disinfection against beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae* apply 1.3 fl. oz. of SANIDATE to

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surfaces at a temperature of 25 to 45 deg C and allow to remain wet for ten (10) minutes. Allow surfaces to drain thoroughly before operations are resumed.

DISINFECTION OF WATER FILTER MEDIA, MEMBRANES AND RELATED COMPONENTS AND SYSTEMS

SANIDATE is an effective disinfectant used for the reduction and removal of bio-organisms on the surfaces of the filter and membrane media, media housings, and related devices and equipment. SANIDATE may be used for filter media or related system components or in Clean in Place (CIP) systems.

Disinfection and or treatment of filter media and membrane in potable water systems should be performed when system is **NOT** in use or online.

For filter media disinfection applications use a rate of 2.5 – 0.25 fl. oz. per gallon, and allow to soak for ten (10) minutes. Drain filter media and then rinse with clean water.

For clean in place (CIP) applications involving filters use a rate of 25 to 6.4 fl. oz. per 100 gallons. Re-circulate solution for a minimum of 10 minutes. Upon completion of cleaning cycle, flush filter housings and or assemblies with clean water.

For direct disinfection of membranes use a solution of 0.25 per gallon, within a pH range of 3-7 and maximum water temperature of 80 degrees F. Allow the membranes to soak for a minimum of 10 minutes. Flush or rinse membranes with clean water after treatment.

For membrane CIP systems use a dilution rate of 25 – 6.4 fl.oz. per 100 gallons within a pH of 3-7 and a maximum water temperature of 80 Degrees F. After thorough draining of the solution, rinse the media thoroughly with clean or sterile water for a minimum of 10 minutes.

To calculate amount of product to be used for CIP systems, identify total volume of all tanks, vessels and piping. Prepare dilution based on sum of all identified tank, vessel and piping volumes.

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DEC 15 2005

PACKINGHOUSE DISINFECTION

SANIDATE is an effective against microorganisms such as *Xanthomonas campestris* (axonopodis) pathovars citrumelo (citrus canker surrogate).

Insecticide,
Fungicide, and Rodenticide Act as
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70299-7

1. Remove gross contamination with a cleaner or other suitable detergent and rinse with potable water.
2. Use SANIDATE at a dilution rate of 1:400 – 1:800 as a general coarse spray to reduce bacterial and fungi contamination of walls, floors, conveyors and harvesting containers.
3. Allow to contact surface for ten (10) minutes. Allow to air dry, do not rinse.

FIELD EQUIPMENT DISINFECTION

SANIDATE may be used to disinfect harvest equipment such as pickers, trailers, trucks (including truck body parts and tires), bins, packing creates, ladders, power tools, hand tools, gloves, rubber boots, pruning shears or other equipment that may transfer *Xanthomonas campestris* (axonopodis) pathovars citrumelo (citrus canker surrogate).

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This product can also be used to disinfect surfaces contaminated with *P. aeruginosa*, *S. choleraesuis* and *S. aureus*.

1. Before disinfection move the field equipment into an area with an impervious surface and with controlled drainage. Ensure that no disinfection solution will be released into the environment.
2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
3. For *Xanthomonas campestris* (axonopodis) pathovars citrumelo (citrus canker surrogate) use SANIDATE at a dilution rate of 1:400 – 1:800 as a general coarse spray. For *P. aeruginosa*, *S. choleraesuis* and *S. aureus* use SANIDATE at a dilution rate of 1:100 (1.3 fl. oz./gal) as a general coarse spray.
4. Allow SANIDATE to contact surface for ten (10) minutes.
5. Allow to air dry, do not rinse.

BACTERIOSTATIC

At 1.3 fl. oz. per 1 gallon of water SANIDATE is effective at inhibiting the growth of bacteria when used in the presence of 400 ppm hard water and organic soil. SANIDATE can be used on floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, and use sites listed on this label made of linoleum, vinyl, porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

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DEC 15 2005

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Store in original containers in a cool, well-ventilated area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water. Do not store in a manner where cross-contamination with other pesticides or fertilizers could occur.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Open dumping is prohibited. If wastes cannot be disposed of according to label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or dispose in a sanitary landfill, or incineration, if allowed by state and local authorities by burning. Stay out of smoke.

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70299-7

WARRANTY - This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, method of application, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.**