



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BioSafe Systems, LLC
22 Meadow Street
East Hartford, CT 06108

MAR 14 2011

Attention: Donna Bishel
Regulatory Specialist

Subject: SaniDate 12.0
EPA Reg. No. 70299-18
Amendment Letter Dated November 10, 2010

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided the following label revisions are incorporated:

- On page 1, the Signal Word "Danger" must be increased in font size so as to appear with sufficient prominence relative to other front panel text and graphic material. See Chapter 3 of the Label Review Manual for the Minimum Type size requirements for the Signal Word.
- On page 2, the Precautionary Statement must be revised to include the statement "Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet."
- On page 2, the phrase "The fruits and vegetables can be sprayed or submerged... followed by adequate draining" must be moved to a new paragraph with a heading separate from "Fruit and Vegetable Processing Waters."
- On page 2, under the section CONTROL OF SPOILAGE AND DECAY CAUSING ORGANISMS IN PROCESS WATER, either qualify the spoilage and decay organisms that are being controlled or delete the words "bacteria and fungi" and "replace with spoilage and decay causing non-public health organisms".
- On page 3, the section FOGGING must be removed. To have this claim additional data must be provided.

- On page 3, delete the proposed section ASCEPTIC FOOD PROCESSING OPERATIONS. Efficacy data were not submitted to support this use. Sterilization data (As described in Antimicrobial Science Policies, Disinfectant Technical Science Section [DIS/TSS] No. 9) that exhibits efficacy against the targeted pest(s) must be submitted to support this use.
- On page 4, under the section, FOR MICROBIAL CONTROL IN EFFLUENT TREATMENT SYSTEMS, either delete or revise the directions for this use. The directions are not acceptable as currently written. The current directions give the impression that the product can be used instead of chlorinated systems intended to treat bacteria of public health concern. Additionally, no directions were given to when this product must be applied in the treatment system.
- On page 5, under the sections, OIL FIELD APPLICATIONS and OIL RECOVERY WELL FLUIDS, FRACTURING FLUIDS OR PIPELINE CLEANING OPERATIONS, the current use direction language in both sections is ambiguous. Typical use patterns for oilfield applications are to treat water in drilling mud, fracing, production, oil recovery, and pipeline cleaning operations. The following changes must be made:
 - Clarification must be included as to distinguish the difference between sections OIL FIELD APPLICATIONS and OIL RECOVERY WELL FLUIDS, FRACTURING FLUIDS OR PIPELINE CLEANING OPERATIONS. Both sections appear to be similar.
 - Biofilm must be deleted from the label. Data must be submitted to support that claim.
 - The language “add a sufficient amount of” must be deleted. Language regarding dosage must specify the exact amount needed to treat the use site.
 - For both OIL FIELD APPLICATIONS and OIL RECOVERY WELL FLUIDS, FRACTURING FLUIDS OR PIPELINE CLEANING OPERATIONS sections, the following must be added:
 - Types of pest controlled must be included. Name of the general type of bacteria controlled, such as “anaerobic bacteria”, “aerobic bacteria”, or “sulfate-reducing bacteria”

Directions for Use

- Directions must indicate where the application is to be made in relation to the operation system. You must specify the where the application is to be made in relation to the operation system it is associated with (i.e. secondary recovery system components, such as pumps, storage tanks, etc...).

- Directions must indicate the equipment used in applying the product, such as injection pump or some other device that may be used.
 - Directions must state the appropriate dosage for particular types of conditions, such as appropriate units. The desired concentration in parts per million (ppm) and dilution ratio(s) must be stated.
 - The appropriate dosage, frequency of treatment and retreatment (hours, days, weeks), and concentration must be stated (if relevant) for either 1) slug dosage, 2) intermittent dosage, 3) continuous dosage or 4) combination of (i.e., 2 and 3 above).
 - Any use limitations, such as water conditions that will alter effectiveness must be stated (i.e., salt content, temperature, and/or pH).

- On page 6, under the TREATMENT OF GREENHOUSE SURFACES AND EQUIPMENT the word “fogger” must be removed from the phrase “Apply solution with mop, sponge, power sprayer, or fogger to thoroughly wet all surfaces.”

- On page 7, under the TREATMENT OF GREENHOUSE IRRIGATION SYSTEMS, the following changes must be included:
 - Delete the language in bold red, AND WATERS. In some instances, water used in greenhouse irrigation systems may be derived from reservoirs for drinking water. Treated water that is used for human consumption must have data to support that use.

 - Delete the phrase “such as.”

 - The new language added to treat “pathogens and bacteria” must be qualified or either deleted. Current language gives the assumption that the product treats both public and non-public organisms. If it will be used to treat public health organisms, then those organisms must be identified in the label and data must be submitted to support those uses. If it is used to treat non-public health organisms, the organisms must be similarly identified; however, no data is required to be submitted. Data for non-public health uses must be on file with your company if the Agency requests to review it.

The Agency approves the following proposed changes to the label:

- On page 1, addition of the EPA manufacturing facility number.

- On page 2, addition of the phrase “For use in food processing operations.”

- On page 2, the Agency approves changing the contact time from 30 to 45 seconds.

- On page 3, addition of the following sections and directions for use: TREATMENT OF PROCESSED FRUIT AND VEGETABLE SURFACES TO CONTROL

GROWTH OF NON-PUBLIC HEALTH MICROORGANISMS THAT CAN CAUSE SPOILAGE. Move the phrase "Note: May cause leaching of treated surfaces, test commodity if unsure."

- On page 4, addition of the following section and use directions, "ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS."
- On page 6, addition of a section and use directions for AIR WASHERS.
- On page 7, The changes made to the TREATMNET OF AGRICULTURAL IRRIGATION WATER AND DRAINAGE DITCHES and TREATMENT OF PLANT PATHOGENS AND SOIL BORNE ORGASMS sections are acceptable.
- On page 12, the proposed optional label claim is acceptable.

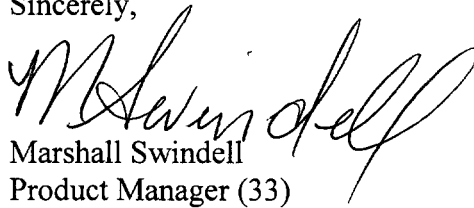
Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

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

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at 703-305-5259.

Sincerely,



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

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through skin. Harmful if swallowed. Do not breathe vapors or spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles, face shield, and rubber gloves when handling. Do not enter an enclosed area without proper respiratory protection. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash before reuse.

PHYSICAL AND CHEMICAL HAZARDS

Corrosive. Strong oxidizing agent. Do not use in concentrated form. Mix only with water in accordance with label instructions. Never bring concentrate in contact with other pesticides, cleaners or oxidative agents.

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 intended as treatment against any public health organism for any use on this label. Uses are intended to treat algal and odor causing bacteria.

- For use in commercial, agricultural, and horticultural irrigation water treatment applications
- Treatment of water for industrial and commercial water treatment systems
- Treatment of fruit and vegetable processing waters
- For use in food processing operations

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with COMMENTS
in EPA Letter Dated:
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The main areas of use include :

- Fruit and vegetable processing facilities
- Commercial, industrial, agricultural and horticultural facilities

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SaniDate® 12.0 works best when diluted with water containing low levels of organic or inorganic materials. Thoroughly rinse out tank with water before mixing concentrate. SaniDate® 12.0 will readily mix with clean water and does not require agitation.

SaniDate® 12.0 is effective on the use sites listed which are manufactured from the following materials; linoleum, formica, vinyl, glazed porcelain, plastic, sealed fiberglass, polyethylene, CPVC, PVC, aluminum, steel, stainless steel, sealed wood, glazed tile, and glass.

CONTROL OF SPOILAGE AND DECAY CAUSING ORGANISMS IN PROCESS WATERS

SaniDate® 12.0 can be used in water or ice that contacts raw or fresh, post-harvest, or further processed fruits and vegetables for the control of bacteria and fungi.

TREATMENT OF FRUIT AND VEGETABLE PROCESSING WATERS

Use SaniDate® 12.0 for the treatment of waters used in the processing of raw fruits and vegetables. Mix SaniDate® 12.0 with water either batch-wise or continuously at a rate of 25.6 to 89.6 fl. oz. of SaniDate® 12.0 solution to 1,000 gallons water. This will provide 200 to 700 ppm of SaniDate® 12.0, or 24 to 85 ppm 100% peracetic acid in the use solution. The fruits and vegetables can be sprayed or submerged in the resulting solution for a minimum contact time of 45 seconds, followed by adequate draining. At this use dilution, SaniDate® 12.0 will control the growth of spoilage and decay causing non-public health organisms in process waters and on the surface of fresh cut or post harvest fruits and vegetables. This product is not intended for control of any public health organisms on fruit and vegetable surfaces.

Use SaniDate® 12.0 may also be used to control the growth of spoilage and decay causing bacterial and fungal diseases on fruits and vegetables in post harvest storage. For post harvest applications, fruits and

vegetables can be sprayed or submerged in the resulting solution for a minimum contact time of 45 seconds, followed by adequate draining.

FOGGING

For raw agricultural commodities, commercially-applied fogging methods may be use provided the dilutions rates of the resultant solution does not exceed those prescribed in this section (24 to 85 ppm 100% peracetic acid in the use solution). Conventional corrosion-resistant fogging devices are recommended. Allow a minimum contact time of 45 seconds. Vacate the area of all personnel prior to, during, and after fogging until the total peroxide concentration is below 1 ppm, or there is no strong odor present, characteristic of acetic acid.

TREATMENT OF PROCESSED FRUIT AND VEGETABLE SURFACES TO CONTROL GROWTH OF NON-PUBLIC HEALTH MICOORGANISMS THAT CAN CAUSE SPOILAGE

Add SaniDate® 12.0 at a dilution rate of 4.0 ounces per 100 gallons of water. Ensure that the solution is thoroughly mixed. This provides 59 ppm of hydrogen peroxide and 38 ppm of peroxyacetic acid. Apply the solution as a spray or dip. Allow a minimum contact time of 45 seconds. No rinse following application is needed. This use complies with the requirements of 21 CFR 173.315 (a) (5). A potable water rinse is not required following application of the diluted solution.

Note: May cause bleaching of treated surfaces, test commodity if unsure.

ASEPTIC FOOD PROCESSING OPERATIONS

This product may be used to achieve commercial sterility of food packaging prior to fill and of equipment used in aseptic food processing applications.

FOOD PACKAGING MATERIALS

Apply SaniDate® 12.0 on the exterior and interior of food containers and closure systems (caps, seals, etc.). Apply 4000 ppm peroxyacetic acid, (a dilution of 1:30 of SaniDate® 12.0) at a minimum temperature of 65 C. The solution must remain in contact with the packaging surface for a minimum of 20 seconds. Rinse containers with sterile water prior to filling with processed food; in lieu of a rinse, films may be mechanically stripped of excess solution. This product may be used on food packaging as an aseptic packaging antimicrobial rinse in food packaging processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation. This product may be used to achieve commercial sterility of non-porous food manufacturing, packaging and filling equipment.

FOOD PACKAGING MATERIALS

SaniDate® 12.0 may be used on manufacturing, filling and packaging equipment.

1. Remove gross soil particles from equipment surfaces.
2. Clean surfaces thoroughly.
3. Rinse thoroughly with potable water.
4. Apply 4000 ppm peroxyacetic acid at a minimum temperature of 65 C.
5. Use immersion, coarse spray or circulation techniques to apply SaniDate® 12.0.
6. Allow contact time of at least 20 seconds.
7. Allow to drain dry.
8. Rinse with sterile water.

This product may be used on equipment used in aseptic packaging antimicrobial rinse in food processing operation that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

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in EPA Letter Dated:

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ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the numbers of non-pathogenic beverage spoilage microorganisms, use a dilution of 1:100 of SaniDate® 12.0. This provides 1200 ppm peroxyacetic acid. After applying antimicrobial rinse, allow containers to drain thoroughly, then rinse with sterile or potable water.

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CONTROL OF ALGAL, FUNGAL, AND ODOR CAUSING BACTERIAL GROWTH IN PULP AND PAPER MILL SYSTEMS FOR FOOD AND NON-FOOD CONTACT PAPER

SaniDate® 12.0 provides an effective means to treat various process waters for slime control. Dosage rates should be increased or decreased depending on the control achieved. **Maximum usage rate must not exceed 2lbs. SaniDate® 12.0 solution per ton (2,000 lbs., dry basis) of pulp or paper produced.**

TREATMENT OF PAPER MACHINE WHITE WATER - SaniDate® 12.0 may be applied within the white water short circulation loop on the paper machine. Apply with either shock, intermittent, or continuous dosing. Shock doses may be applied for 1 to 2 hours, as necessary, whereas intermittent doses are applied 1 to 12 times per day, for a duration of 5 to 60 minutes each. For either shock or intermittent dosing, apply 2.5 to 102 fl. oz. of SaniDate® 12.0 per 1000 gallons of white water, producing a peak concentration of 20 to 800 ppm of SaniDate® 12.0 during dosing. This is approximately equivalent to a peak dose of 2 to 100 ppm 100% peracetic acid. For continuous dosing, apply 2.5 to 25 fl. oz. of SaniDate® 12.0 to 1000 gallons of process water, producing a peak concentration of 20 to 200 ppm of SaniDate® 12.0. This is approximately equivalent to 2 to 25 ppm 100% peracetic acid.

CATALASE CONTROL IN DEINKING WATER LOOPS - SaniDate® 12.0 may be applied to the inlet lines going to de-inking water storage following clarification. Apply with either shock, intermittent, or continuous dosing. Shock doses may be applied for 10 to 60 minutes as necessary. Apply 1.7 to 4.2 gallons SaniDate® 12.0 per 1000 gallons recirculation water, producing a peak concentration of 1700 to 4200 ppm SaniDate® 12.0 during dosing. This is approximately equivalent to a peak dose of 200 to 500 ppm 100% peracetic acid. For intermittent doses, apply 1 to 12 times per day, for a duration of 10 to 60 minutes. Apply 0.8 to 2.1 gallons SaniDate® 12.0 per 1000 gallons of water, producing a peak concentration of 800 to 2100 ppm of SaniDate® 12.0 during dosing. This is approximately equivalent to a peak dose of 100 to 250 ppm 100% peracetic acid. For continuous dosing, apply 0.2 to 1.4 gallons SaniDate® 12.0 to 1000 gallons of process water, producing a peak concentration of 200 to 1400 ppm of SaniDate® 12.0. This is approximately equivalent to 25 to 170 ppm 100% peracetic acid.

TREATMENT OF RAW AND PROCESS WATER - SaniDate® 12.0 may be applied to water at the inlet of the process water system or any other suitable point. Apply with either shock, intermittent, or continuous dosing. Shock dosing may be applied for a duration of 1 to 2 hours, as necessary, whereas intermittent dosing is applied for 2 to 15 minutes, 4 to 100 times per day. For either shock or intermittent dosing, apply 0.16 to 0.8 gallons SaniDate® 12.0 per 1,000 gallons of water producing a peak concentration of SaniDate® 12.0 of 160 ppm to 800 ppm during dosing. This is approximately equivalent to a peak dose of 20 to 100 ppm 100% peracetic acid. For continuous dosing applications, apply 0.01 to 0.3 gallons SaniDate® 12.0 to 1,000 gallons of water, producing a peak concentration of 10 to 300 ppm of SaniDate® 12.0. This is approximately equivalent to 1 to 36 ppm 100% peracetic acid.

FOR MICROBIAL CONTROL IN EFFLUENT TREATMENT SYSTEMS- Use SaniDate® 12.0 to treat sewage and wastewater effluent associated with public and private wastewater treatment plants. SaniDate® 12.0 can be applied by itself, directly to the effluent, or in conjunction with an appropriate activator, such as UV light. Apply SaniDate® 12.0 at any point where microbial control is essential. Apply 4 to 83 gallons of SaniDate® 12.0 per 1,000,000 gallons of wastewater (0.5 to 10 ppm of peracetic acid). NOTE: the dosing rate for individual facilities will depend on the nature of effluent (level of microbial control) and the local microbial discharge limit. Therefore, adjust the dosing rates to the levels appropriate for your facility. Do not exceed the maximum dose limit of 83 gallons of SaniDate® 12.0 per 1,000,000 gallons of waste water (or 10 ppm of peracetic acid). The PAA concentration will rapidly decline after

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treatment. The maximum amount of PAA that can be discharged from the treatment facility is 1.0 ppm PAA. Use an appropriate PAA test kit or analyzer as recommended by BioSafe Systems to ensure this level is not exceeded. Contact your BioSafe Systems technical representative for guidance on treatment regimes.

CONTROL OF ALGAL, FUNGAL, AND SLIME-FORMING BACTERIAL GROWTH IN INDUSTRIAL WATER

INDUSTRIAL WASTE TREATMENT

Use SaniDate® 12.0 to control algae, bacteria and fungi in industrial wastewater treatment and sewage systems. SaniDate® 12.0 may be applied to water at the inlet of the process water system or any other suitable point. Apply with either shock, intermittent, or continuous dosing. Shock dosing may be applied for a duration of 1 to 2 hours, as necessary, whereas intermittent dosing is applied for 2 to 15 minutes, 4 to 100 times per day. For either shock or intermittent dosing, apply 0.16 to 0.8 gallons SaniDate® 12.0 per 1,000 gallons of water producing a peak concentration of SaniDate® 12.0 of 160 ppm to 800 ppm during dosing. This is approximately equivalent to a peak dose of 20 to 100 ppm 100% peracetic acid. For continuous dosing applications, apply 0.01 to 0.3 gallons SaniDate® 12.0 to 1,000 gallons of water, producing a peak concentration of 10 to 300 ppm of SaniDate® 12.0. This is approximately equivalent to 1 to 36 ppm 100% peracetic acid. Do not discharge treated effluent without notifying local sewage treatment plant authorities.

OIL FIELD APPLICATIONS (Not approved for use in California)

SaniDate® 12.0 may be used as an algaecide, fungicide and or a slimicide for oilfield applications. It will control biofilm deposits on pumps, pipe work, heat exchangers, filters and all down hole applications associated with oilfield systems. Add a sufficient amount of SaniDate® 12.0 directly to the well fluid or fracturing fluid to achieve a residual level of 50-200 ppm of peracetic acid, or use 50 fl ounces per 1000 gallons or one gallon of SaniDate® 12.0 per 500 gallons of fluid.

OIL RECOVERY WELL FLUIDS, FRACTURING FLUIDS OR PIPELINE CLEANING OPERATIONS (Not approved for use in California)

When used as directed, this product will control the growth of bacteria such as anaerobic sulfite forming bacteria and aerobic slime forming bacteria which impair the efficacy of well fluids and fracturing fluids. Add a sufficient amount of SaniDate® 12.0 directly to the well fluid or fracturing fluid to achieve a residual level of 50-200 ppm of peracetic acid, or use 50 fl ounces per 1000 gallons or one gallon of SaniDate® 12.0 per 500 gallons of fluid. SaniDate® 12.0 may be added and premixed with the well fluid or fracturing fluid prior to the oil field operation or maybe added directly to the blender during operations. Be sure rapid mixing of the treated water is achieved.

CONTROL OF ALGAL, FUNGAL, AND ODOR CAUSING BACTERIAL GROWTH FOR NON-FOOD CONTACT PAPER USES

TREATMENT OF STARCH USED FOR SIZING ON THE PAPER MACHINE - Apply SaniDate® 12.0 directly to the starch storage tank or through the recirculation loop. Apply with either shock, intermittent, or continuous dosing. Shock doses may be applied for 1 to 2 hours, whereas intermittent doses may be applied for 5 to 60 minutes up to 12 times per day. For either shock or intermittent dosing, apply 0.8 to 5 gallons SaniDate® 12.0 per 1,000 gallons of starch solution to achieve 100 to 600 ppm 100% peracetic acid. For continuous dosing applications, apply 0.08 to 1.7 gallons SaniDate® 12.0 per 1,000 gallons of starch solution, producing a peak concentration of approximately 10 to 200 ppm 100% peracetic acid.

TREATMENT OF CLAYS USED AS COATINGS AND FILLERS ON THE PAPER MACHINE - Applications may be made at the recirculation loop or directly to the agitated slurry storage tank. Apply with either shock, intermittent, or continuous dosing. Shock doses may be applied for 1 to 2 hours, as necessary, whereas intermittent doses may be applied for 5 to 60 minutes, 1 to 12 times per day. For either shock or intermittent dosing, apply 5.12 to 102 fl. oz. SaniDate® 12.0 to 1,000 gallons clay slurry solution producing a peak concentration of approximately 50 to 100 ppm 100% peracetic acid. For

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continuous dosing applications, apply 5.12 to 102 fl. oz. SaniDate® 12.0 to 1,000 gallons of process water, producing a peak concentration of 5 to 100 ppm 100% peracetic acid.

COATINGS PRESERVATION - SaniDate® 12.0 can be used as an in-container preservative for the control of bacteria and fungi in water-based coatings such as paper coatings. Add 12.8 to 89.6 fl. oz. of SaniDate® 12.0 solution to 1,000 gallons water. This will provide 100 to 700 ppm of SaniDate® 12.0, or 12 to 85 ppm 100% peracetic acid.

TREATMENT OF DISPERSED PIGMENTS - SaniDate® 12.0 can be used in the control of bacteria and fungi in the manufacture and storage of dispersed pigments such as kaolin clay, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, magnesium silicate and kieseguhr used in paint and paper production. Add 0.12 to 0.6 lb. of SaniDate® 12.0 to each 1,000 lbs. of fluid. This will provide 120 to 600 ppm of SaniDate® 12.0, or 15 to 70 ppm 100% peracetic acid.

CONTROL OF ALGAL, FUNGAL, AND ODOR CAUSING BACTERIAL GROWTH IN INDOOR, CLOSED LOOP, NON-POTABLE, NON-FOOD CONTACT WATER SYSTEMS

TREATMENT OF RAW AND PROCESS WATER - (such as heat exchanger system water, boiler water, wet scrubber water) - SaniDate® 12.0 may be applied to water at the inlet of the water system or any other suitable point. Apply with either shock, intermittent, or continuous dosing. Shock dosing may be applied for a duration of 1 to 2 hours, as necessary, whereas intermittent dosing is applied for 2 to 15 minutes, 4 to 100 times per day. For either shock or intermittent dosing, apply 0.16 to 0.8 gallons SaniDate® 12.0 per 1,000 gallons of water producing a peak concentration of SaniDate® 12.0 of 160 ppm to 800 ppm during dosing. This is approximately equivalent to a peak dose of 20 to 100 ppm 100% peracetic acid. For continuous dosing applications, apply 1.3 to 38.4 fl. oz. SaniDate® 12.0 to 1,000 gallons of water, producing a peak concentration of 10 to 300 ppm SaniDate® 12.0. This is approximately equivalent to 1 to 35 ppm 100% peracetic acid.

TREATMENT OF COOLING WATER SYSTEMS - (such as cooling towers, evaporative condensers) Severely fouled systems should be cleaned before treatment. Discontinue use of chlorine or bromine products prior to using this product. SaniDate® 12.0 should be added to the system directly and not mixed with other chemicals or additives prior to dosing. Other chemicals should be added separately. Check compatibility of SaniDate® 12.0 with any other chemicals or additives prior to use. Contamination with certain chemicals could result in lack of efficacy. Add SaniDate® 12.0 at a point in the system where uniform mixing and even distribution will occur such as the cooling tower basin sump. Shock doses may be applied for 1 to 2 hours, as necessary, whereas intermittent doses are applied for 5 to 60 minutes 1 to 100 times per day. For either shock, intermittent or continuous dosing, apply 1.3 to 9.0 fl.oz. of SaniDate® 12.0 solution per 1,000 gallons of water. This will provide 10 to 70 ppm of SaniDate® 12.0, or 1 to 9 ppm of 100% peracetic acid. Repeat treatment as required to maintain control.

AIR WASHERS- This product maybe used to control bacteria and biofouling in industrial air washing/scrubbing systems. The air washer must have operational and effective mist elimination systems. Prior to use of this product, heavily fouled systems must be pre-cleaned using the appropriate cleaner. Continuous dosing methods will require 2-7 ppm and intermittent dosing methods will require 7-14 ppm of peracetic acid depending on the type of systems and the level of microbiological control desired.

CONTROL OF ALGAL, FUNGAL AND ODOR CAUSING BACTERIAL GROWTH ON NON FOOD CONTACT GREENHOUSE WATERING SYSTEMS

TREATMENT OF GREENHOUSE SURFACES AND EQUIPMENT - (such as glazing, plastic, pots, flats, trays, cutting tools, benches, work areas, walkways, floors, walls, fan blades, watering systems, coolers, storage rooms, structures and equipment) – Clean surfaces before treatment. Sweep and remove all plant debris, and use power sprayer to wash all surfaces to remove loose dirt. Use a dilution of 1:600 of SaniDate® 12.0 for all non-porous surfaces that have been pre-cleaned with water. Apply solution with mop, sponge, power sprayer or fogger to thoroughly wet all surfaces. Cutting tools may be soaked to

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ensure complete coverage. Allow surfaces to stay wet with solution for a minimum of five (5) minutes. Heavy growths of algae and fungi may have to be scrubbed off following application. Repeat treatment as required to maintain control.

TREATMENT OF GREENHOUSE EVAPORATIVE COOLERS – Treat contaminated surfaces with a dilution of 1:600 of SaniDate® 12.0. Allow surfaces to stay wet with solution for a minimum of five (5) minutes. For maintenance, treat cooler water once a week with a dilution of 1:2,000 of SaniDate® 12.0 for every gallon of cooling water.

TREATMENT OF GREENHOUSE IRRIGATION SYSTEMS AND WATERS- (such as flooded floors, flooded benches, recycled water systems, drip trickle, capillary mats, sprinkler systems, humidification and misting systems) For shock treatment of irrigation lines, use a dilution rate of 1:1,000-1:5,000. Allow solution to remain in lines for 12-48 hours. Flush by opening flush valves or laterals to avoid clogging emitters. To target specific pathogens, apply per 1,000 gallons of water: bacteria - 3.2 – 25.6 fl. oz. (1:5,000 – 1:40,000 dilution), algae - 6.4 – 25.6 fl. oz. (1:5,000 – 1:20,000 dilution) or fungi/oomycetes – 8.3 – 25.6 fl. oz. (1:5,000 – 1:15,000 dilution). For recycled water, use a rate of 1:5,000-1:40,000. For maintenance, treat clean water with a dilution of 1:50,000 – 100,000 of SaniDate® 12.0 as needed.

CONTROL OF ALGAL, FUNGAL, AND SLIME-FORMING BACTERIAL GROWTH IN AGRICULTURAL IRRIGATION SYSTEMS AND WATER

TREATMENT OF AGRICULTURAL IRRIGATION WATER AND DRAINAGE DITCHES

Use SaniDate® 12.0 to treat water to suppress / control algae, bacteria, fungi and plant pathogenic organisms in agricultural irrigation and drainage water and ditches. To target specific pathogens, apply per 1,000 gallons of water: bacteria, 3.2 – 25.6 fl. oz. (1:5,000 – 1:40,000 dilution); algae, 6.4 – 25.6 fl. oz. (1:5,000 – 1:20,000 dilution), or fungi/oomycetes, 8.53 – 25.6 fl. oz. (1:5,000 – 1:15,000 dilution). For clean well water, or as a preventative application, Apply 0.6 to 1.3 fluid ounces of SaniDate® 12.0 per 1,000 gallons of water. Product can be simply added to the body of water, as the residual control will allow for even distribution throughout the water column. For heavily contaminated water, apply SaniDate® 12.0 at a dilution rate of 1:5,000-1:40,000. Allow solution to disperse for five (5) minutes before irrigating. Apply SaniDate® 12.0 as needed to control and prevent algae growth; apply more often in times of higher water temperatures.

TREATMENT OF AGRICULTURAL IRRIGATION SYSTEMS

Use SaniDate® 12.0 to suppress / control algae, bacteria, fungi and plant pathogenic organisms in drip trickle irrigation systems, center pivot, lateral move, end tow, side wheel roll, traveler, solid set/overhead sprinklers, hand move or flood basin irrigation systems. Treat contaminated water at a dilution of 1:1000 - 1:5,000. For shock treatment of irrigation lines, use a dilution rate of 1:1,000-5,000. Allow solution to remain in lines for 12-48 hours. Flush by opening flush valves or laterals to avoid clogging emitters. For maintenance, treat clean water with a dilution of 1:50,000 to 1:100,000 of SaniDate® 12.0 as needed. Allow solution to disperse for five (5) minutes before irrigating. Refer to Chemigation Directions for Use for specific instructions on using this product through irrigation systems.

TREATMENT OF PLANT PATHOGENS AND ASSOCIATED DISEASES (Not approved for use in California)

FOLIAR SPRAY/DRENCH/CHEMIGATION FOR CONTROLLING FOLIAR PLANT PATHOGENS

Use SaniDate® 12.0 to suppress and control foliar plant pathogens and their associated diseases such as – *Alternaria* – *Anthraco*se – *Aphanomyces* – Black Spot - *Botrytis* (grey mold) - Downy Mildew – *Erwinia*, *Fusarium* (root rot) - Leaf Spot - *Phytophthora* (blights) – *Plasmopara* - Powdery Mildew - *Pseudomonas* - *Pythium* - *Rhizoctonia* - Rust - Scab - Smut - *Thielaviopsis* – *Uncinula* (powdery mildew) – *Xanthomonas* - Wilts & Blights. Use SaniDate® 12.0 at a rate of 1:1,000-1:5,000 as a foliar spray, drench or through the irrigation system at the time of seeding or transplanting, as well as a periodic treatment throughout the plant's life. Multiple applications can be made, as there is no mutational resistance with this product.

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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.**SOIL DRENCH/CHEMIGATION FOR CONTROLLING SOILBORNE PLANT PATHOGENS**

Use SaniDate® 12.0 to suppress and control soilborne plant pathogens and their associated diseases such as *Fusarium* (root rot) - *Phytophthora* (blight and root rots)- *Pythium* - *Rhizoctonia* - *Ralstonia solanacearum* (brown rot, bacterial wilt), - *Sclerotinia sclerotiorum* (white mold) - *Sclerotium rolfsii* - *Thielaviopsis* - *Verticillium*. Apply SaniDate® 12.0 at a rate of 1 : 5,000 – 1 :10,000 as a soil drench or through the irrigation system, as a soil treatment, at the time of seeding or transplanting, as well as a periodic treatment throughout the plant's life. Multiple applications can be made, as there is no mutational resistance with this product. Apply in sufficient water for sufficient duration to distribute the application evenly to the treated area. Apply to moderately moist soils. Follow use directions for Chemigation. Do not apply this product through any irrigation system unless the chemigation instructions are followed.

CHEMIGATION INSTRUCTIONS**General Requirements -**

- 1) Apply this product only through a drip system or sprinkler system, including flood, and drip (trickle) irrigation systems.
- 2) Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from non-uniform distribution of treated water.
- 3) If you have questions about calibration, you should contact State Extension Service specialists, equipment manufacturers or other experts.
- 4) Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.
- 5) A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.
- 6) Posting of areas to be chemigated is required when 1) any part of a treated area is within 300 feet of sensitive areas such as residential areas, labor camps, businesses, day care centers, hospitals, in-patient clinics, nursing homes or any public areas such as schools, parks, playgrounds, or other public facilities not including public roads, or 2) when the chemigated area is open to the public such as golf courses or retail greenhouses.
- 7) Posting must conform to the following requirements. Treated areas shall be posted with signs at all usual points of entry and along likely routes of approach from the listed sensitive areas. When there are no usual points of entry, signs must be posted in the corners of the treated areas and in any other location affording maximum visibility to sensitive areas. The printed side of the sign should face away from the treated area towards the sensitive area. The signs shall be printed in English. Signs must be posted prior to application and must remain posted until foliage has dried and soil surface water has disappeared. Signs may remain in place indefinitely as long as they are composed of materials to prevent deterioration and maintain legibility for the duration of the posting period.
- 8) All words shall consist of letters at least 2.5 inches tall, and all letters and the symbol shall be a color which sharply contrasts with their immediate background. At the top of the sign shall be the words KEEP OUT, followed by an octagonal stop sign symbol at least 8 inches in diameter containing the word STOP. Below the symbol shall be the words PESTICIDES IN IRRIGATION WATER.

Specific Requirements for Chemigation Systems Connected to Public Water Systems -

- 1) Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.
- 2) Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

SaniDate® 12.0

EPA Reg. No. 70299-18

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- 3) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 4) The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 5) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Specific Requirements for Sprinkler Chemigation -

- 1) The system must contain a functional check valve, vacuum relief valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- 2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- 5) The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.
- 7) Do not apply when wind speed favors drift beyond the area intended for treatment.

Specific Requirements for Flood Chemigation -

- 1) Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from backflow if water flow stops.
- 2) The systems utilizing a pressurized water and pesticide injection system must meet the following requirements:
 - a. The system must contain a functional check valve, vacuum relief valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
 - b. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
 - c. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
 - d. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
 - e. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

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- f. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock. Under the Federal Insecticide, Fungicide, and Rodenticide Act, SaniDate is registered for the pesticide, registered under EPA Reg. No.

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Specific Requirements for Drip (Trickle) Chemigation -

- 1) The system must contain a functional check valve, vacuum relief valve and low-pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
- 2) The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
- 3) The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
- 4) The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
- 5) The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
- 6) Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being filled with a system interlock.

Application Instructions -

- 1) Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
- 2) Determine the treatment rates as indicated in the directions for use and make proper dilutions.
- 3) Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
- 4) Do not apply SaniDate 12.0 in conjunction with any other pesticides or fertilizers; this has the potential to cause reduced performance of the product. Avoid application in this manner.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in original containers in a cool, well-vented 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.

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 (Containers greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling if available.

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WARRANTY

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of BIOSAFE SYSTEMS LLC or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold BIOSAFE SYSTEMS and Seller harmless for any claims relating to such factors.

BIOSAFE SYSTEMS warrants that this product conforms to the *chemical* description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above when used in accordance with directions under normal use conditions. This warranty does not extend to the use of the product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or BIOSAFE SYSTEMS, and Buyer and User assume the risk of any such use. BIOSAFE SYSTEMS MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, NOR ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall BIOSAFE SYSTEMS or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF BIOSAFE SYSTEMS AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF BIOSAFE SYSTEMS OR SELLER, THE REPLACEMENT OF THE PRODUCT.

BIOSAFE SYSTEMS and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of BIOSAFE SYSTEMS.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAR 14 2011

Under the Federal Insecticide,
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Optional Label Claims

- Microbiocide
- Easy to use
- Activated Peroxygen chemistry
- Contains no phosphates
- Deodorizes
- Leaves no residue
- Scent free
- Chlorine free
- Treats and controls mold and mildew
- Controls algae
- Control algal and fungal growth
- Controls odor causing bacteria
- Controls slime forming bacteria
- Control plant pathogenic organisms
- Controls spoilage and decay causing organisms in fruit and vegetable processing waters
- Controls odors
- SaniDate 12.0 is an economical concentrate that can be used with a mop and bucket, trigger spray, sponge, or by soaking.
- SaniDate 12.0 will not leave a grit or soap scum.
- *When used as directed, this product will deodorize surfaces in places where bacterial growth can cause malodors.*
- SaniDate 12.0 inhibits bacterial growth on moist surfaces and deodorizes by controlling microorganisms that cause offensive odors. *Not for use in California*
- SaniDate 12.0 inhibits bacterial growth on moist surfaces and deodorizes by killing microorganisms that cause offensive odors.
- SaniDate 12.0 is a concentrate formulation designed for use in commercial, institutional, and industrial operations.
- SaniDate 12.0 controls the growth of odor-causing and slime forming bacteria.
- SaniDate 12.0 is formulated to effectively eliminate offensive odors caused by mold and mildew.
- SaniDate 12.0 can be used in agricultural irrigation water
- SaniDate 12.0 can be used in greenhouse irrigation water
- Use SaniDate 12.0 in cooling water systems
- For control of algal, fungal, slime forming bacterial growth
- Use SaniDate 12.0 on greenhouse surfaces
- *A post harvest treatment for the prevention and control of plant pathogenic diseases on all fruits and vegetables and other agricultural crops in dump tanks, hydro coolers and process waters.*
- *A treatment for the prevention and control of plant pathogenic diseases on surfaces, equipment and structures used in processing post-harvest commodities.*
- Industrial Waste Treatment
- Oil Field Treatments
- Controls foliar plant pathogens
- Controls soil-borne plant pathogens
- For use in food processing operations

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