

63838-1

9-12-2002

1/9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 12 2002

Mike Harvey
EnviroTech Chemical Services, Inc.
P.O. Box 577470
Modesto, CA 95357

**Subject: BioSide HS 5%
EPA Reg. No. 63838-1
Your Re-Submissions Dated 6/6/02 (label)
and 5/25/02 (revised CSF) and 7/19/02 (inquiry about front end rejection)**

The re-submissions referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide a revised basic pre- and post-reaction Confidential Statement of Formula (CSF) dated 5/25/02 which deletes H2SO4 so that the end use ppm concentrations of each constituent comply with food contact sanitizer and tolerance exemptions for the fruit and vegetable uses, and provides a revised label in response to the EPA letter dated 5/22/02, would be acceptable after you submit five copies of a revised label which fully satisfies the required changes listed below.

General -

Unless you have data to the contrary, we assume that deletion of H2SO4 has no significant impact on product efficacy. If this is not the case, please advise.

Also note that the percent purities of the formula constituents (50%, 60%, etc.) listed on the post-reaction CSF do not apply because all are assumed to be 100% due to the chemical reaction and final equilibrium state.

Please enclose a copy of this letter with your response to help in the approval process.

Label Page 1/6

No changes required.

Label Page 2/6

1. Change, "Use dilutions up to 2.3 oz of this product per 5 gallons of water (197 ppm peroxyacetic acid) may be used but concentrations greater than this amount must be rinsed with sterile water, or by using a sanitizing rinse of BioSide HS 5%", to the following, "Use dilutions up to 2.3 oz of this product per 5 gallons of water (197 ppm peroxyacetic acid) may be used". The Agency will not allow higher food contact sanitizer doses than permitted by the applicable 21CFR or 40 CFR regulation.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2/9

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Label Page 3/6

- 1. In the food contact sanitizing sections for conveyors, tableware, and final bottle rinse, add a statement requiring a 60 second minimum contact time with adequate draining, and no rinse needed.
- 2. In the fogging section, for clarity change, "Fog desired areas using one quart per 1000 cu. ft. of room area with a 0.3% to 1.5% solution of this product (2 oz to 10 oz BioSide HS 5% per 5 gallons of water), to the following, "Fog desired areas using one quart of a 0.3% to 1.5% solution of this product (2 oz to 10 oz BioSide HS 5% per 5 gallons of water) per 1000 cu. ft. of room area".
- 3. In the final sanitizing bottle rinse section, add a requirement for adequate drying. A sterile water rinse is not required by EPA (EPA registered food contact sanitizers do not have a potable or sterile water rinse, even though the some industry practice may be contrary).
- 4. Move the two "Notes" for mechanical and manual operations to the beginning of the sanitization section. These notes refer to all sanitizing uses, not just the bottle rinse where they are presently located.

Label Page 4/6

- 1. Delete the "asphalt" and "porcelain" ("glazed porcelain" is acceptable) use sites. These are porous, and not hard. (ie., asphalt).
- 2. In the combined disinfection/cleaning section, delete the "do not rinse" statement and replace with "Surfaces that may directly or indirectly contact food must be rinsed with potable water before operations resume. A rinse for non-food contact surfaces is optional".
- 3. The title for the poultry/trucks/coops/crates section does not accurately match the use sites in this section because more animals than just poultry are involved (eg., animal hospitals, livestock, etc.). Therefore, add a more accurate "animal and poultry" type component in the title and throughout the this section.

For this section and the animal housing section, add the missing use directions listed in DSS/TSS #18 (Farm premises) and #19 (Poultry). Just as one example, statements about treatment of animal halters and ropes are required. Refer to other EPA labels for reference (eg., EPA Reg. No. 10324-17).

Label Page 5/6

Move the egg sanitization section to the food contact section where it logically fits.

Label Page 6/6

- 1. In the continuous/intermittent section, add the actual ounces of product per gallons to get 1 ppm of peroxyacetic acid.

CONCURRENCES							
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SURNAME							
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4/9

BioSide™ HS 5% (Antimicrobial Solution)

BioSide™ HS 5% is a peroxyacetic acid-based sanitizer/disinfectant developed for the following uses:

Institutional/Industrial Sanitizer and Disinfectant for Previously Cleaned Hard Non-Porous Food Contact Surfaces in: Dairies, Wineries, Breweries, Food and Beverage Plants, Poultry Egg Facilities, and Animal Housing.

Hard, Non-Porous Surface Disinfection in: Hospitals, Schools, Industrial Facilities, Office Buildings, Veterinary Clinics,

Bacteria, Fungi, and Slime Control in: Cooling Water and Evaporative Cooler Systems, Reverse Osmosis and Ultra Filtration Systems, Fruits and Vegetables

Active Ingredients:

Peroxyacetic Acid 4.9%
Hydrogen Peroxide 26.5%

Inert Ingredients: 68.6%

Total: 100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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EPA Registration No. 63838-1
EPA Est. No. 69994-CA-01

Before Using This Product, Please Read This Entire Label Carefully

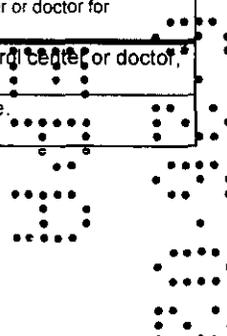
KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF SWALLOWED:	Call a 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING	Take off contaminated clothing and shoes. Rinse skin immediately with plenty of soap and water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
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.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
QUESTIONS ? 1-209-581-9576	Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
NOTE TO PHYSICIAN:	Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured By:
Enviro Tech Chemical Services, Inc.
PO Box 577470
Modesto, CA 95357



VER. 5-28-02

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

Physical or Chemical Hazards

STRONG OXIDIZING AGENT. CORROSIVE. Mix only with potable water at 60-80° F. Product must be diluted in accordance with label directions prior to use. BioSide™ HS 5% is not combustible; however, at temperatures exceeding 156°F, decomposition occurs releasing oxygen. The oxygen released could initiate combustion.

Environmental Hazards:

This pesticide is toxic to birds, fish and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of the National Pollution Discharge System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage plant authority.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

SANITIZATION

BioSide™ HS 5% peroxyacetic acid sanitizer is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, filters, evaporators, pasteurizers, and aseptic equipment in dairies, brewers, wineries, beverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. This product is effective as a sanitizer when solution is prepared in water of up to 400 ppm hardness as CaCO₃. This product has demonstrated greater than 99.999% reduction of organisms after 30 seconds exposure period in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study.

Sanitizing Food Contact Surfaces

This product can be used in Federally Inspected Meat and Poultry Facilities as a sanitizer. Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1.0 ounce BioSide™ HS 5% dissolved in 5 gallons of water (0.16% v/v concentration, or 86 ppm active peroxyacetic acid). At this dilution BioSide™ HS 5% is effective against Staphylococcus aureus, Escherichia coli, Salmonella choleraesuis, and Listeria monocytogenes.

Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to sanitizing solution for a period of at least 60 seconds or more if specified by a governing code. Drain thoroughly and allow to air dry. Do not rinse. Use dilutions up to 2.3 oz of this product per 5 gallons of water (197 ppm peroxyacetic acid) may be used, but concentrations greater than this amount must be rinsed with sterile water, or by using a sanitizing rinse of BioSide HS 5%.

6/9

SEP 12 2002

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Sanitization of Conveyors and Equipment for Meat, Poultry, Seafood, Fruit and Vegetables

BioSide HS 5% is effective against the gram negative and gram positive organisms Staphylococcus aureus, Salmonella choleraesius, Escheria coli and Listeria monocytogenes.

For use in the sanitizing of, or for washing or rinsing of conveyors and equipment, apply a solution of this product using 1.0 to 1.5 oz per 5 gallons of water (86 ppm to 129 ppm active peroxyacetic acid). Apply sanitizer solution to the return portion of the conveyor or equipment using coarse spray or similar means of wetting surfaces, so as to affect draining and prevent puddling.

Sanitizing Eating, Drinking And Food Prep Utensils

Remove gross food particles by a prescrape, a preflush and when necessary, a presoak treatment. Wash with a recommended detergent. Rinse with clean water.

Sanitize in a solution of 1.0 ounces BioSide™ HS 5% dissolved in 5 gallons of water. Immerse all utensils for at least 60 seconds or contact time specified by a governing sanitary code.

Drain and air dry.

Sanitizing Tableware

For sanitizing tableware in low temperature warewashing machines, inject BioSide™ HS 5% into the final rinse water at a concentration of 1.0 ounce BioSide™ HS 5% dissolved in 5 gallons of water. Do not exceed 0.16 % v/v. Air dry.

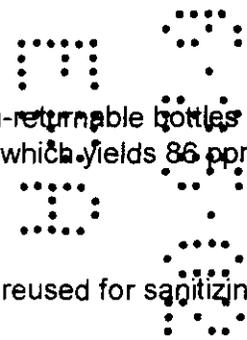
To insure that BioSide™ HS 5% sanitizer concentration does not fall below 0.1%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your technical service representative for assistance and further information on sanitizing tableware in warewashing machines.

FOGGING IN FILLING, PACKAGING, AND DISPENSING ROOMS OR AREAS:

BioSide HS 5% is used as an adjunct to acceptable manual cleaning and disinfection of room surfaces. Prior to fogging remove food products and packaging materials from the room or area or carefully protect them. Fog desired areas using one quart per 1000 cu. ft. of room area with a 0.3% to 1.5% solution of this product (2 oz. to 10 oz BioSide HS 5% per 5 gallons of water). Conventional corrosion resistant fogging devices are recommended. Vacate the area of all personnel prior to, during and after fogging until the hydrogen peroxide concentration is below 0.5 ppm, or there is no strong odor present, characteristic of acetic acid. Allow surfaces to drain thoroughly before operations are resumed. For food contact surfaces, concentrations above 2.3 oz of this product per 5 gallons of water require a sterile or sanitizing rinse prior to resuming operations.

FINAL SANITIZING BOTTLE RINSE

BioSide™ HS 5% may be used as a final sanitizer rinse for returnable and non-returnable bottles at a 0.16%-0.36% dilution (1.0 oz.-2.3 oz. BioSide™ HS 5% in 5 gallons of water), which yields 86 ppm-197 ppm active peroxyacetic acid.



NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared daily or more often if the solution becomes diluted or soiled.

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NON FOOD CONTACT HARD SURFACE DISINFECTION

BioSide™ HS 5% disinfects as it cleans in one operation. BioSide™ HS 5% can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, asphalt, porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass. Surfaces that may directly or indirectly contact food must be rinsed with potable water before operations resume.

Areas of use in hospitals use BioSide™ HS 5% for surgical and obstetrical suites; housekeeping services; physical therapy departments; nursing services; autopsy facilities. Also use BioSide™ HS 5% in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

Combination Disinfection and Cleaning

BioSide™ HS 5% is effective against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Trichophyton mentagrophytes and Escherichia coli 0157:H7 at 0.23% (1.5 oz./5 gal.) in hard water (400 ppm as CaCO₃) and 5% organic soil loading on hard nonporous surfaces. For heavily soiled areas a pre-cleaning step is required, followed by a potable water rinse. Apply solution with a mop, cloth, sponge, brush, etc... or by soaking or immersion 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, wet vacuum pickup, or by draining. Do not rinse. Prepare a fresh solution daily or when it becomes soiled or diluted.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

BioSide™ HS 5% 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, BioSide™ HS 5% is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding equipment. In addition BioSide™ HS 5% will deodorize those areas which are generally hard to keep smelling fresh, such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use. Remove all poultry and feeds from premises, trucks, coops and crates. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with a detergent and rinse with water. Saturate surfaces with a 0.16% (1.0 oz./5gal.) solution of BioSide™ HS 5% for a period of 10 minutes. Ventilate buildings, coops and other closed spaces. Do not house poultry on employ equipment until treatment has been absorbed, set or dried.

Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.

See your technical representative for specific recommendations for all cleaning and rinsing requirements. All treated equipment that will contact food, feed, or drinking water must be rinsed with potable water before reuse.

Disinfection And Deodorizing Of Animal Housing Facilities (Barns, Kennels, Hutches, Etc.)

8/9

Remove animals and feed from facilities. Remove litter, waste matter, and gross soils. Empty all troughs, rack and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply a 0.16% (1.0 oz./5 gal.) solution of BioSide™ HS 5% with a mop, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

CONTROL OF SLIME FORMING BACTERIA IN COOLING WATER SYSTEMS (COOLING TOWERS, EVAPORATIVE CONDENSERS).

Severely fouled systems should be cleaned before adding the BioSide™ HS 5% solution. BioSide™ HS 5% should be added in the system directly and not mixed with any other chemicals or additives. Discontinue the use of chlorine or bromine products prior to using this product. Contamination with other chemicals could result in product decomposition. Add BioSide HS 5% at a point in the system where uniform mixing and even distribution will occur.

For slug treatment add 20 oz. of product per 1000 gallons of process water. Repeat as necessary until microbiological control is evident. Thereafter, to maintain control, use 0.3 to 1.5 lbs. (4-20 fl. oz. per 1000 gallons of process water) (2-9 ppm active peroxyacetic acid) as a continuous or intermittent slug treatment. Continuous dosing methods usually require 2.0-5.0 ppm active peroxyacetic acid (4-10 fl. oz. per 1000 gal of process water) to achieve adequate control.

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FOR SANITIZING OF CASING OR SHELL EGGS

To sanitize clean shell eggs intended for food or food products, spray with a solution of BioSide HS 5% by diluting 1.0 oz. product with 5 gallons of potable water (providing 86 ppm peroxyacetic acid). The solution must be equal to or warmer than the eggs, but not to exceed 130 F. Wet eggs thoroughly and allow to drain. Eggs that have been sanitized with this product may be broken for use in the manufacture of egg products without a prior potable water rinse. Eggs must be reasonably dry before casing or breaking. The sanitizing solution must not be reused for sanitizing eggs.

REVERSE OSMOSIS (RO) AND ULTRA FILTRATION (UF) CLEANING

BioSide HS 5% may be used in the sanitization of ultra filtration and reverse osmosis membranes and their associated piping systems. This product may be added continuously to the feed water stream to prevent accumulation of biological matter between sanitization episodes. This product is not for use in kidney dialysis equipment. This product may not totally eliminate all vegetative microorganisms in RO or UF membranes and their associated piping systems due to their construction or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. Prior to using this product check with membrane manufacturer to confirm compatibility of membranes to peroxyacetic acid solutions.

Batch Sanitation of UF and RO Systems: Isolate incompatible equipment, such as carbon filters and ion exchangers, and UV equipment. Clean system with an appropriate cleaner and follow with RO permeate water or potable water. Remove mineral deposits with an acidic cleaner, rinse as before. Fill entire system with water and add up to 1% of this product by volume. This will equal 550 ppm peroxyacetic acid and 2970 ppm hydrogen peroxide. Recirculate the sanitizing solution through the piping and membrane system at 20° C for 10 minutes minimum, or up to 4 hours, depending on the severity of cleaning to be done. Open and close process valves and solenoids to be sure all parts are in contact with the solution. Rinse the system with RO permeate or potable water until residual peroxygen concentration is below 3 ppm.

This product may also be added continuously to the feed water stream, between sanitizing episodes, to aid in minimizing the regrowth or accumulation of biological matter. The peroxygen residual in the system will vary with the design and usage characteristics of the system. Periodically monitor and adjust the concentration as necessary.

9/9

Continuous or Intermittent Addition: For continuous addition do not exceed 20 ppm BioSide HS 5%, which equals 1 ppm active peroxyacetic acid. For occasional intermittent feed, do not exceed 80 ppm active peroxyacetic acid, which equals 1 oz. of this product per 5 gallons of feed water. Do not use the continuous feed method for potable water or direct food contact systems.

FRUIT AND VEGETABLE WASHING:

This product may be used to help control spoilage or decay-causing bacteria and fungi on fruits and vegetables. Fruits and vegetables should be continuously sprayed, using coarse spray, or submerged using a solution containing no more than 1 oz. BioSide HS 5% per 20 gallons of water. This will equal 21 ppm active peroxyacetic acid. Allow this process to continue for a minimum of 2 minutes contact time. Remove excess water or allow to drain. If using the submersion method, prepare a fresh solution daily or when it becomes visibly soiled or diluted. A final potable water rinse is not necessary.

NOTE: This product at its use dilution is compatible with stainless steel and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

Storage and Disposal

Storage: Never return BioSide™ HS 5% to the original container after it has been removed. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute BioSide™ HS 5% with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedure for Leak or Spill: Stop leak if this can be done without risk. Shut off ignition sources: no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal. BioSide™ HS 5% which is to be discarded, should be disposed of as hazardous waste after contacting the appropriate local state or Federal agency to determine proper procedures.

Container Disposal: >5 gallon plastic drums: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by State and local authorities, by burning. If burned, stay out or smoke.

>5 gallons plastic tote bin liners: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out or smoke.

BioSide™ HS 5%

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