

87518-1

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

NOV 28 2011

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

Henry Dao, President
HSP USA LLC
3111 Route 38, Suite 11, #310
Mount Laurel, N.J. 08054

Subject: (Hsp20)
EPA Registration Number 87518-1
Amendment Dates: July 6, 2011 and August 17, 2011
Notification Date: November 4, 2011

Dear Mr. Dao:

The Agency has reviewed your submission in accordance with continuing registration under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, and determined the actions to be acceptable with the following comments:

- On page 8, move the Environmental Hazards section to the top of the Precautionary Statements;
- Under the Storage and Disposal heading revise the precaution to read "Do not contaminate water, food or feed by storage or disposal";
- Add the word "Pesticide" in front of Storage and Disposal as marked;

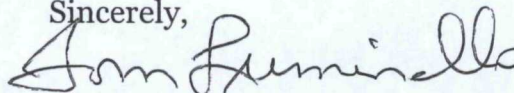
In summary, your request to revise the basic Confidential Statement of Formula (CSF) has been reviewed and determined to be acceptable. The CSF dated July 20, 2011 has been accepted as the new basic CSF and will supersede the previous basic CSF. In addition, the certified lower limit was revised to an equivalent of 130 ppm based on our review of MRID 485317-02. A copy of our chemistry review, D392343, is enclosed. MRID 485317-01 was submitted in support of the Corrosion Characteristics and Storage Stability data requirements as required by the registration of this product and support the removal of the shelf life of 60 days.

In support of the lower certified limit claim, MRID 485317-01 was reviewed and determined to be acceptable. A copy of our review of your confirmatory product performance, D387746, is enclosed.

In addition, some changes to the label were requested by the Agency. These changes were submitted as a Notification on November 4, 2011 and are now included as part of the revised amendment.

A stamped copy of the accepted with comments labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling. If you have any questions, please contact Tom Luminello by telephone, (703) 308-8075, or by e-mail at luminello.tom@epa.gov.

Sincerely,



Monisha Harris
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510 P)

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Broad Spectrum and Multi-purpose Disinfectant

Kills drug resistant MRSA and VRE | Destroys fungus
Eliminates odors and kills odor-causing bacteria

(Hsp₂O)[®]

Formulated Water-Based Disinfectant

Ready to Use

Active Ingredient:	
Hypochlorous Acid	0.018%
Other Ingredients.....	99.982%
Total.....	100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for additional precautionary statements

Manufactured by:
HSP USA, LLC
3111 Route 38, Suite 11, #310
Mount Laurel, NJ 08054

EPA Registration Number: 87518-1
EPA Establishment Number: 87518-NJ-002

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 28 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), this pesticide is registered under EPA Reg. No.

87518-1

OVERVIEW

Description:

(Hsp₂O) is a disinfectant for use on hard non-porous inanimate surfaces. (Hsp₂O) is a super-oxidized, pH-neutral water based solution. It is a broad-spectrum, ready-to-use product that is especially useful in hospital patient care areas, dental offices, households, institutions, commercial facilities including childcare facilities, health clubs, laboratories, veterinary and pet care facilities, food processing, agricultural facilities, transportation and hospitality facilities, industrial areas.

When used according to the direction for use, this product disinfects hard non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, baked enamel and glazed tile in the above application areas.

General Claims:

- Broad spectrum, pH neutral, water based disinfectant
- Alcohol and bleach free
- Kills germs
- Multi-purpose cleaner or disinfectant
- Multi-surface cleaner or disinfectant
- Non-corrosive or Non-staining of surfaces including stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, baked enamel and glazed tile
- Non-flammable
- Kills drug resistant MRSA and VRE
- Contains non-VOC-emitting ingredients
- Destroys fungus
- Cleans, disinfects, deodorizes
- Colorless and odorless
- Durable and stable solution
- No special handling or disposal requirements
- No Personal Protective Equipment (PPE) required
- Effective under ambient conditions
- Easy - and or - convenient way to disinfect
- Ready to use hospital cleaner or disinfectant
- Instrument presoak disinfectant
- Bactericide - or - Bactericidal
- Fungicide - or - Fungicidal
- Disinfects and deodorizes by killing odor causing bacteria while chemically neutralizing their odor
- Eliminates - or - Reduces odor caused by bacteria
- Fight(s) - and/or Kill (s) - and / or - Effective against (see pathogens list below)
- Kills a wide range of pathogens (see pathogens list below)
- This product meets EPA standards for hospital disinfection

ACCEPTED
 VERIFICATION
 m.l. - Date:
 NOV 28 2011

This is a disinfectant,
 and does not act as
 a pesticide,
 reg. under EPA Reg. No.

87518-1

Microbiocidal Activity:

(Hsp₂O) disinfectant solution kills the following germs:

Pathogen

- Staphylococcus aureus
- Pseudomonas aeruginosa
- Salmonella enterica
- Methicillin-resistant Staphylococcus aureus (MRSA)
- E. coli* O157:H7
- Vancomycin resistant Enterococcus faecalis (VRE)
- Acinetobacter baumannii
- Trichophyton mentagrophyte

Contact Time

- 10 minutes
- 10 minutes
- 10 minutes
- 10 minutes
- 10 minutes
- 10 minutes
- 10 minutes
- 10 minutes

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...icide,
... EPA Reg. No.

87518-1

DIRECTIONS FOR USE

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

DISINFECTION APPLICATIONS

(Hsp₂O) is a disinfectant for use on hard non-porous inanimate surfaces. It is a broad-spectrum, ready-to-use product that is especially useful in hospital patient care areas, dental offices, households, institutions, commercial facilities including childcare facilities, health clubs, laboratories, veterinary and pet care facilities, food processing, agricultural facilities, transportation and hospitality facilities, industrial areas.

When used according to the directions for use, this product disinfects hard non-porous surfaces including: stainless steel, chrome, glass, vinyl, glazed porcelain, non-porous plastics, baked enamel and glazed tile in the above application areas.

Hard, Non-porous Indoor Surface Disinfection :

To [clean and] disinfect [and deodorize] Hard, Non-Porous Surfaces. For heavily soiled areas, a preliminary cleaning is required. Apply [wipe or dip] (Hsp₂O) at 250ppm FAC to hard, non-porous surface with a cloth, wipe, mop, sponge, fog or coarse spray. Treated surface must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes. Small non-porous objects can be soaked in (Hsp₂O) without dilution. Allow objects to soak for 10 minutes.

Other Claims:

- Disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous surfaces at different sites (see sites and surfaces list below)
- Use where hazards of cross-contamination between treated surfaces is of primary importance at different sites (see sites and surfaces list below)

- Cleans and disinfects hard non-porous surfaces at different sites (see sites and surfaces list below)

For Use on Hard, Non-Porous Surface at the Following Sites (including but not limited to):

<p>Healthcare:</p> <ul style="list-style-type: none"> • Hospitals including emergency rooms, critical and intense care units, neonatal units, isolation areas and quarantine rooms etc. • Health clinics • Doctor's offices • Dental clinics and offices • Ophthalmic and optometric facilities, and eye surgical centers 	<p>Hospitality & Household</p> <ul style="list-style-type: none"> • Hotels • Motels • Bed and Breakfasts • Hostels • Mobile homes • Homes • Condos • Apartments • Nursing homes • Retirement homes
<p>Food Processing & Service:</p> <ul style="list-style-type: none"> • Food processing facilities (food contact surfaces must be rinsed with potable water after treatment) • Commercial and institutional kitchens, food service facilities (food contact surfaces must be rinsed with potable water after treatment) • Restaurant and bars (food contact surfaces must be rinsed with potable water after treatment) • Cafeterias, deli, fast food restaurants (food contact surfaces must be rinsed with potable water after treatment) 	<p>Commercial Facilities</p> <ul style="list-style-type: none"> • Supermarkets, convenience stores, and liquor stores (food contact surfaces must be rinsed with potable water after treatment) • Office buildings • Fitness centers, gymnasiums, and locker rooms • Public recreational facilities – movie theatres, bowling alleys, indoor playgrounds, camp grounds, and clubs • Barber shops, hair and nail salons, tanning salons, and spas • Public restrooms, and dressing rooms • Veterinarian clinics and offices, animal hospitals, animal housing and grooming facilities, pet shops, and zoos • Laboratories

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<p>Industrial Applications</p> <ul style="list-style-type: none"> • Pharmaceutical and medical device producing establishments • Manufacturing facilities • Industrial facilities • Beverage and breweries (beer, wine, liquor production) • Warehouses and distribution centers • Paper manufacturing facilities 	<p>Institutions & Government:</p> <ul style="list-style-type: none"> • Schools (Pre-, elementary, grade, high) • College and University • Day care centers • Government office buildings • Prisons and correctional facilities • Police stations • Fire stations • Barracks and other military accommodations • Post offices • Customs and immigration facilities
<p>Public Transportation:</p> <ul style="list-style-type: none"> • Cruise ships • Ships and boats • Planes, trains, and buses • Trucks and cars • Taxis and limo • Trailers and campers 	<p>Agriculture:</p> <ul style="list-style-type: none"> • Live stock facilities • Live poultry facilities • Dairy farms • Arboretum • Green houses and gardens

This product is not for outdoor residential consumer use.

For Use on Hard, Non-Porous Indoor Surface at the Following Sites (includes but not limited to):

<ul style="list-style-type: none"> • Appliances • Anesthesia Machines • Animal Cages • Automobile interiors • Bathroom fixtures • Bathtubs • Bed railings • Bidets • Cabinets • Chairs (sealed wood and metal) • Computers • Counters • Cribs • Dental irrigation equipment surfaces • Desks • Diaper changing tables • Door knobs • Drinking fountains 	<ul style="list-style-type: none"> • Eyeglasses • Fax machines • Faucets • Floors • Garbage cans • Gardening tools • Glazed tile • Gymnasium / fitness equipment • Haircutter blades • Hair dryers • Hand rails • Headsets • High Chairs • Keyboards • Litter boxes • Metal • Manicure table • Microwave oven exteriors • Mirrors • Nail files • Non-critical medical equipment and devices 	<ul style="list-style-type: none"> • Oxygen hood surface • Physical therapy equipment • Railings • Razors • Refrigerator exteriors • Respiratory equipment • Salon surfaces • Saunas • Scissors • Seats • Shampoo bowls • Showers • Sinks • Stainless steel • Steam rooms • Stoves • Stovetops • Stretchers • Surgical beds / tables 	<ul style="list-style-type: none"> • Tabletops • Telephones • Toilet exteriors • Trashcans • Tubs • Tweezers • Urinal exteriors • Walls • Workstations
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MEDICAL APPLICATIONS

For Pre-cleaning Instruments, Equipment and Surfaces Prior to Disinfection: Apply (Hsp₂O) directly to the surface. Allow to remain wet for 30 seconds. Wipe surface using a paper or cloth towel to dry. Discard towel.

For Disinfecting Non-critical Instruments and Equipment Surfaces: Thoroughly pre-clean surfaces prior to disinfection with (Hsp₂O). Apply (Hsp₂O) directly to pre-cleaned surfaces, thoroughly wetting area to be disinfected. Allow the surface to be wet for 10 minutes at room temperature (69°F / 20°C). Wipe surface using a paper or cloth towel to dry. Discard towel.

For Use As a Pre-cleaning Immersion Solution: Fill appropriate size container with a sufficient amount of (Hsp₂O) as to allow for complete submersion of instruments. Place instruments into (Hsp₂O) disinfectant solution, cover and allow to soak for 10 minutes at room temperature (69°F / 20°C). Remove and rinse the instruments. Follow with appropriate disinfection process by following directions for that product. When the solution becomes diluted or visibly soiled, change solution.

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For Use As a Pre-cleaning Spray: Place instruments into suitable container. Spray (Hsp₂O) disinfectant solution onto instruments so as to thoroughly wet all surfaces. Allow to remain wet for 30 seconds. Remove the instruments. Follow with appropriate cleaning and disinfection process by following directions for that product. When the solution becomes diluted or visibly soiled, change solution.

For Use As an Ultrasonic Cleaning Solution: Thoroughly pre-rinse instruments under (Hsp₂O) or running water to remove visible gross debris. Fill ultrasonic unit with (Hsp₂O) to a level which allows complete submersion of instrument. Immerse instruments into solution and activate ultrasonic unit for 10 minutes. Remove instruments. Follow with appropriate disinfection process by following directions for that product. When the solution becomes diluted or visibly soiled, change solution.

For Use As a Manual Cleaner: Thoroughly pre-rinse instruments under (Hsp₂O) or running water to remove visible gross debris. Fill container with (Hsp₂O) to a level which allows complete submersion of instrument. Immerse instruments into solution and scrub for 30 seconds. Allow the instruments to remain submerged for 10 minutes. Remove instruments. Follow with appropriate disinfection process by following directions for that product. When the solution becomes diluted or visibly soiled, change solution.

For Disinfecting Non-critical, Pre-cleaned Medical Instruments: Instruments must be thoroughly pre-cleaned to remove excess organic debris, rinsed and thoroughly dried. (Clean and rinse lumens of hollow instruments before filling with solution or before immersion.) Using either a soaking tray or an ultrasonic unit, immerse instruments into (Hsp₂O) solution and scrub for 10 minutes. Remove instruments. Wipe surface using a paper or cloth towel to dry prior to use. Discard towel. The solution must be discarded after each use.

Note: Critical and semi-critical devices must be followed by an appropriate terminal sterilization / high level disinfection process.

The product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization of high level disinfection.

VETERINARY / ANIMAL FACILITIES APPLICATIONS

(Hsp₂O) is a disinfectant that is especially useful in veterinary practices, animal care, animal laboratory, zoos, and pet shops.

To clean and disinfect hard nonporous surface, remove all animals and feeds from premises. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with (Hsp₂O) for a period of 10 minutes. Immerse handling and restraining equipment such as leashes, muzzles, halters,

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The Dept. of Insecticides,
U.S. Environmental Protection Agency,
Washington, D.C. 20460
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or ropes. Allow equipment and housing to completely dry after use and before returning animals.

AGRICULTURAL APPLICATIONS

For live stock or poultry facilities or dairy farms, remove all the animals and feeds from the premises, vehicles, coops, crates, and enclosures. Remove all the litter, manure and droppings from the floors, walls and surfaces of barns, pens chutes and other facilities occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Remove gross filth. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with (Hsp₂O) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure. Rinse with potable water before reuse.

For cut flowers or plants, dilute (Hsp₂O) (250ppm FAC) with water by 1:10 ratio to spray on the flowers or plants, and put in the vase to mitigate and retard the growth of non-public health micro-organisms affecting the health and longevity of the flowers or plants. Repeat and change water if it gets murky.

OIL AND GAS APPLICATIONS

Frac Water: For typical water treatment, mix 10 US gallons of (Hsp₂O) (250ppm FAC) with 990 US gallons of frac water to 2.5ppm FAC to mitigate and retard the growth of non-public health micro-organisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells: For typical water treatment, slug dose 336 US gallons of (Hsp₂O) (250ppm FAC) into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters: For typical produced water treatment, mix 42 gallons of (Hsp₂O) (250ppm FAC) with 958 US gallons of produced water to 10.5ppm FAC to retard the growth of non-public health microorganisms.

Heater Treaters: Hydrocarbon Storage Facilities & Gas Storage Wells: For typical storage facility treatment, mix 252 gallons of (Hsp₂O) (250ppm FAC) into the water phase of the mixed hydrocarbon / water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water: For typical water flood injection water treatment, mix 42 US gallons of (Hsp₂O) (250ppm FAC) with 958 US gallons of injection water to 10.5ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines: For typical transmission line treatment, slug dose 840 gallons of (Hsp₂O) (250ppm FAC) into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRBs, reduce microbiologically influenced corrosion (MIC).

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PRECAUTIONARY STATEMENTS

PHYSICAL OR CHEMICAL HAZARDS

Do not use this product with other household or industrial chemicals such as toilet bowl cleaners, rust removers, acids, or products containing ammonia. Prolonged contact with metal may cause pitting or discoloration.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatic organisms.

[For containers \geq 5 gallons] Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal.

Pesticide

Storage: Store (Hsp₂O) in its original sealed container at room temperature, away from direct sunlight and heat to avoid deterioration. If the product leaks or spills from the container, rinse the area with water and let it air dry.

Pesticide

Disposal: If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program.

Container Disposal:

[For containers < 5 gallons] Non-refillable Container. Do not refill or reuse container. Triple rinse then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

[For containers \geq 5 gallons] Non-refillable Container. Do not refill or reuse container. Triple rinse as follows: Empty the remaining content into application equipment or a mix tank. Fill container $\frac{1}{4}$ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat the procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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with COMMENTS
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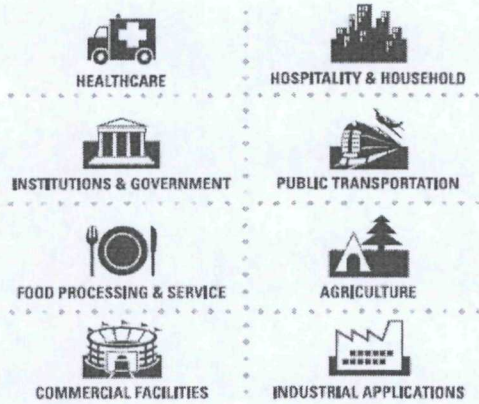
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OPTIONAL TEXT

WARRANTY

HSP USA LLC warrants that this product conforms to the product specification on this label and is reasonable fit for the purposes set forth in the Directions of Use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE.

(Hsp₂O)[®]



ACCEPTED
with COMMENTS
in EPA Master Label:

NOV 28 2011

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

87518-1