



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 30, 2018

Bob MacDonald
Agent
Medivators Inc.
14605 28th Ave North
Minneapolis, MN 55447

Subject: Notification per PRN 98-10 – Minor Corrections and adding Patent Information
Product Name: Minncare Cold Sterilant
EPA Registration Number: 52252-4
Application Date: 11/09/2018
Decision Number: 546501

Dear Mr. MacDonald:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Page 2 of 2
EPA Reg. No. 52252-4
Decision No. 546501

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Aline Heffernan". The signature is fluid and cursive, with a long horizontal flourish extending to the right.

Zeno Bain, Product Manager 33
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

NOTIFICATION

52252-4

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/30/2018

MINNCARE® COLD STERILANT [Master Label]

For use in sanitizing of Reverse Osmosis Membranes and their associated distribution systems. Also for the sterilization and disinfection of hard surfaces and non-porous food contact surfaces.

For use in the following locations;

Industrial Laboratories
Pharmaceutical Manufacturers
Medical Products Manufacturers
Electrical Utility Companies
Dairies and Pasteurizing Facilities
Beverage and Food Processing Plants
Breweries/Wineries

Hospitals (as a disinfectant)
University Laboratories
Semi-Conductor Manufacturers
Cosmetic Manufacturers
Bio Tech Companies
Animal Hospitals
Veterinary Clinics

Read the Minncare Cold Sterilant label and application notes before using this product.

Failure to follow directions for use per package insert may result in user injury.

This product must be diluted with Purified Water prior to use.

Active Ingredients

Hydrogen Peroxide	22.0%
Peroxyacetic Acid	4.5%

Inert Ingredients

73.5%

Total	100.0%
-------	--------

Net Contents: _____

KEEP OUT OF REACH OF CHILDREN

DANGER – PELIGRO

See {side panel} {Directions for Use} for additional precautionary statements.

EPA Reg. NO.: 52252-4
EPA Est. NO.: 52252-MN-01

(Medivators logo)

U.S. Pat. No. 6,261,457 and foreign counterparts.
© xxxx Medivators Inc.

MINNCARE® is a registered trademark of Medivators Inc.

LOT: MFD: EXP:

Manufactured in the USA by:
Medivators Inc
14605 28th Avenue North
Minneapolis, Minnesota 55447 U.S.A.
Toll Free: +1.800.444.4729
www.medivators.com

Minnicare Cold Sterilant Master Label
{ } indicates alternate text
[] Administrative text – not on final label

52252-4
13a

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals.

DANGER – PELIGRO

Corrosive. Causes irreversible eye damage. Harmful if absorbed through skin. Do not get in eyes, on skin, or on clothing. Avoid contact with skin. Prolonged or frequent repeated skin contact may cause an allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum. Using tobacco or using the toilet. Remove contaminated clothing and wash hands before reuse. Caution should be used when applying indoors because pets may be at risk.

FIRST AID	
IF INHALED:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR ON CLOTHING:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment.
IF IN EYES:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment.
IF SWALLOWED:	<ul style="list-style-type: none">• 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 by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3387.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Chemtrec at 1-800-424-9300 for emergency medical treatment information.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

PRECAUTIONARY STATEMENTS Cont.

Personal Protective Equipment (PPE)

Handlers must wear: Goggles or face shield, and protective rubber gloves.

Environmental Hazards

This pesticide is toxic to birds, fish and aquatic invertebrates

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

Physical and Chemical Hazards

This product contains an oxidizing agent.

PRODUCT {EFFICACY}{CLAIMS}

- Sterilant 100X dilution, 11 hours 20°C
- Sporicidal 100X dilution, 11 hours 20°C
- Bactericidal 100X dilution, 11 hours 20°C
- Viricidal 100X dilution, 11 hours 20°C
- Hepatitis B 100X dilution, 11 hours 20°C
- HIV-1* 100X dilution, 11 hours 20°C
- Fungicidal 100X dilution, 11 hours 20°C
- Effective against non-tuberculous mycobacterium (chelonae abscessus) 100X dilution, 11 hours 20°C
- Cleaner/Sanitizer (Non-food contact surfaces) 32X dilution, 10 min., 20°C
- (food contact surfaces) 320X dilution, 1 min., 25°C
- Staphylococcus aureus and Escherichia coli
- Hospital Disinfectant 100X dilution, 10 min., 20°C
- Pseudomonas
- Broad Spectrum Disinfectant 100X dilution, 10 min., 20°C
- Germicidal Spray Disinfectant 100X dilution, 10 min., 20°C
- RO Membrane Sanitizer 100X dilution, 36 min., 20°C

***KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces / objects likely to be soiled with blood or bodily fluids which can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the sterilant.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONTACT TIME: Leave surfaces wet for 11 hours.

GENERAL DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
DO NOT USE AFTER EXPIRATION DATE.

Do not allow Minncare Cold Sterilant to mix with alkaline substances such as bleach (Sodium Hypochlorite).

If spilled, flush away with large quantities of water. Use purified water when diluting Minncare Cold Sterilant.

Minncare Cold Sterilant is a single-use product not intended for reuse. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled.

DIRECTIONS FOR STERILIZATION

Minnicare Cold Sterilant may be used as a sterilant in any application other than health care setting/hospital. For use on hard, non-porous surfaces such as plastics, stainless steel objects or containers; glass used by laboratories, manufacturers of pharmaceuticals, medical products, and cosmetics. Examples include glassware, laboratory instruments, containers, etc. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with purified water, mechanical action, or by detergent cleaning followed by a water rinse. Dilute Minnicare Cold Sterilant 100X (1-part Minnicare plus 99 parts purified water). Do not store diluted Minnicare Cold Sterilant for use as a sterilant; once diluted, use immediately. Immerse the item to be sterilized in a sufficient volume of diluted Minnicare Cold Sterilant to cover the item and fill all passages requiring sterilization. Hold in the sterilizing solution for a minimum of 11 hours at 20°C (68°F). Remove items after 11 hours and rinse with sterile water until effluent testing shows acceptable levels when tested with Minnicare Residual Test Strips.

DIRECTIONS FOR HOSPITAL DISINFECTION

Minnicare Cold Sterilant is to be used on hard, non-porous surfaces such as plastics, glass, or stainless steel in settings such as hospitals, clinics, or physician's offices. Examples include counters, bed rails, bathroom fixtures and bedpans. This product is **not** to be used as a terminal high-level disinfectant on any critical/semi-critical medical device. Remove any obvious debris or organic material from the surface to be disinfected. This can often be accomplished by rinsing with purified water, mechanical action or by detergent cleaning followed by a water rinse. Dilute Minnicare Cold Sterilant 100X (1-part Minnicare Cold Sterilant plus 99 parts purified water). Once diluted, the solution must be used within seven (7) days. Immerse the item to be disinfected in sufficient volume of diluted Minnicare Cold Sterilant to cover the item and fill all passages requiring disinfecting. Hold in the disinfecting solution for a minimum of 10 minutes. Remove items after 10 minutes and rinse with sterile water until effluent shows acceptable levels when tested with Minnicare Residual Test Strips. This product may be used to pre-clean or decontaminate critical/semi-critical medical devices **prior** to sterilization or high-level disinfection.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING:

This product may be used in fogging as an adjunct following regular cleaning and disinfecting procedures for hard room surfaces.

Prior to fogging, remove or carefully protect all food products and packaging materials. Ensure room is properly ventilated. Vacate all personnel from the room during fogging and do not allow personnel into the room until the hydrogen peroxide air concentration has been verified to be less than or equal to 0.5 ppm. Fog areas using 1 to 10 ml of concentrated Minnicare solution per cubic meter of room volume using a 0.3 to 10% aqueous diluted solution using any fogging equipment that is capable of achieving the desired droplet size of 0.5 to 150 microns and is constructed of compatible materials. Review the operations manual provided by the fogging equipment manufacturer for specific directions on the use of this equipment. Dilution directions: To obtain an aqueous diluted solution of 0.3%, add 0.3 ml of concentrated Minnicare solution to 99.7 ml of high purity water (i.e. RO or DI). To obtain an aqueous diluted solution of 10%, add 10 ml of concentrated Minnicare solution to 90 ml of high purity water (i.e. RO or DI). Allow surfaces to dry thoroughly before operations are resumed.

Note: Once diluted, the solution must be used within 7 days. Discard any unused diluted solution

DIRECTIONS FOR SANITIZING OF REVERSE OSMOSIS MEMBRANES

Minnicare Cold Sterilant is recommended for sanitizing reverse osmosis membranes and their associated distribution systems. This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. Minnicare Cold Sterilant may not totally eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. The possibility of recontamination by the incoming water supply may exist. Minnicare Cold Sterilant should be used in a sanitation program, which includes bacteriological monitoring of the entire RO water system.

Minnicare Cold Sterilant may be used for reverse osmosis (RO) systems, which are compatible with diluted hydrogen peroxide solutions. The Minnicare Cold Sterilant has a shelf life of one year. Minnicare Cold Sterilant should not be stored at its 1% use dilution since this may compromise its effective concentration. This product is not registered for use on kidney dialyzers and dialysis machines.

The RO manufacturer should be consulted prior to use of Minnicare Cold Sterilant to determine the temperature and pH range acceptable for the particular membranes. At a 100X dilution (1% concentration), the pH range for Minnicare Cold Sterilant is 3.0-3.5. RO water systems vary in design according to the particular needs of the user. Because of the variations in materials of construction at different facilities, some systems may have components of pumps, gasket, etc. that are not compatible with long term exposure to Minnicare Cold Sterilant. Minnicare Cold Sterilant is to a degree, corrosive to copper, brass, iron and certain other metals. Minnicare Cold Sterilant has also exhibited a decreased resistance to latex and Buna-N with extended exposure. Minnicare Cold Sterilant Solution has been found compatible with typical system materials such as stainless steel. It is also compatible with polypropylene, high-density polyethylene, polysulfone, Teflon, polycarbonate, neoprene, ABS, nylon, acrylic silicone, Plexiglass, ethylene, propylene, VITON, FLUOREL, PVC and CPVC.

Because of the individuality of the RO water system in design and construction as well as the quality of raw feed water, all RO water does not contain the same components. Dependent upon your particular system, all or portions of the following procedure may be for sanitizing.

Biological or organic fouling of the membrane or other parts of the system should be removed with the appropriate cleaner. It is important to follow the membrane manufacturer's recommended cleaning procedure. After cleaning, flush the system. Mineral deposits should be removed with an acidic cleaner prior to sanitizing the membrane. Again, follow the membrane manufacturer's recommended cleaning procedure. Then flush the unit with RO permeate. The presence of iron or other transition metals, in conjunction with the hydrogen peroxide in Minnicare Cold Sterilant, could cause membrane degradation. Prepare a 1% solution (1-part Minnicare Cold Sterilant to 99 parts water) by adding the Minnicare Cold Sterilant to permeate water. Fill the entire water circuit to be sanitized with a 1% solution and allow the diluted solution to reach a minimum temperature of 20° (68°F). Do not exceed the membrane manufacturer's recommended temperature. Recirculate the 1% Minnicare Cold Sterilant solution until the entire system is filled. Allow the elements to soak in the 1% Minnicare Cold Sterilant solution for a minimum of 36 minutes at 20°C (68°F).

Rinse the RO system and check for residuals by following the directions on the Minncare Residual Test Strips label. The residual test strip should indicate less than 2ppm. Rinse times will vary depending on the size of the RO system. Residual sanitizer that may enter the system because of chemical rebound can be eliminated by diverting product water to drain for a short period of time.

DIRECTIONS FOR USE AS A GERMICIDAL DISINFECTANT SPRAY

For use as a germicidal spray on hard surfaces such as floors, walls, bathroom fixtures, vinyl or Formica surfaces. Dilute 100X with purified water. Note: Once diluted, the solution must be used within seven (7) days. Discard any unused diluted solution. Spray onto surfaces using a plastic spray bottle. Allow product to remain on surface for 10 minutes. Let air dry or rinse with purified water. Drain off excess water, if possible, and allow to dry.

DIRECTIONS FOR USE AS A CLEANER/SANITIZER

(NONFOOD CONTACT SURFACES)

For use on hard, non-porous surfaces such as plastics, stainless steel objects or Formica. Examples include counter tops, walls, floors, bedrails, bathroom fixtures, etc. Using water or mechanical action, remove heavy soil and gross filth from hard non-porous surfaces such as Formica, stainless steel, or plastic. Dilute 32X with purified water. Note: Once diluted, the solution must be used within seven (7) days. Discard any unused diluted solution. Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled. Apply solution to surface or immerse items to be sanitized in the solution. Minncare Cold Sterilant may be applied by cloth, mop or sponge. Allow 10 minutes of contact time. Rinse with purified water, drain excess, if possible, and allow to air dry.

DIRECTIONS FOR USE AS A CLEANER/SANITIZER (FOOD CONTACT SURFACES)

Minncare Cold Sterilant may be used to sanitize hard, non-porous surfaces such as glass or stainless steel used in fillers, pipelines, silos processing vats, bulk tanks and utensils used in dairies, food processing plants, wineries and breweries. Using water or mechanical action, remove heavy soil, gross food particles or gross filth from hard surfaces such as Formica, stainless steel, glass or plastic. Using an appropriate detergent or cleaner, wash surfaces or objects. Rinse with potable water. Remove and food products or packaging materials from the room or cover completely. Dilute Minncare Cold Sterilant at 2 ounces to 5 gallons of water. Use fresh solution with each use. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled. Dip, spray, brush or fill equipment with solution and allow to sit at least 1 minute at 75°F (25°C). Allow to drain well. Do not rinse. Blow or air dry.

USES

Primarily intended use with surfaces such as:

- Reverse Osmosis Membranes and Associated Distribution Systems
- Plastic Items
- Stainless Steel Objects or containers e.g. bedpans, tanks
- Hard Surfaces e.g. counters, sinks, bulk tanks, etc.
- Floors, Walls, Bathroom Fixtures, Vinyl surfaces
- Formica surfaces
- Glass

STORAGE AND DISPOSAL

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

Pesticide Storage

Store in shipping carton. Do not expose to direct sunlight. Maintain temperature below 75°F (25°C). Avoid contact with combustible materials. Avoid contamination from any source, including metals, dust, etc. Such contamination may cause rapid decomposition, generation of large quantities of oxygen gas and high pressures. Store in original closed container. NEVER TAMPER WITH VENT

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site by dilution in a sanitary sewer or at an approved waste disposal facility. 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 of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤ 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill container $\frac{1}{4}$ full of 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 flow begins to drip. Repeat this procedure two more times.

(For ≥ 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten enclosures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip, it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.