

52252-4

1-23-2003

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

52252-4

Date of Issuance:

JAN 23 2003

NOTICE OF PESTICIDE:

Registration
 Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Minnicare Cold Sterilant

Name and Address of Registrant (include ZIP Code):

Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document for Peroxy Compounds RED. EPA has reregistered the above named product subject to the comments recorded in the succeeding paragraph. This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

1. Make the following label changes:

- a. Revise the EPA Registration No. to read "EPA Reg. No. 52252-4"

Signature of Approving Official:

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

JAN 23 2003

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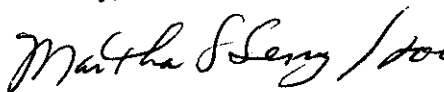
EPA Registration No. 52252-4

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

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

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**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 | Hospitals |
| Pharmaceutical Manufacturers | University Laboratories |
| Medical Products Manufacturers | Semi Conductor Manufacturers |
| Electrical Utility Companies | Cosmetic Manufacturers |
| Dairies and Pasteurizing Facilities | Bio Tech Companies |
| Beverage and Food Processing Plants | Breweries/Wineries |

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	<u>73.5%</u>
Total	100.0%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 23 2003

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

5-2-2-5-2-4

Net Contents: _____

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See side panel for additional precautionary statements.

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

(Minntech logo)

Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447 U.S.A
Telephone: (763) 553-3300
Toll Free: (800) 328-3345
Fax: (763) 553-3387
E-mail: info@minntech.com

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PRECAUTIONARY STATEMENTS

JAN 29 2003

Hazard to Humans and Domestic Animals.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
5-2-75-2-4

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 advice.
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.	

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PRECAUTIONARY STATEMENTS Cont.

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Personal Protective Equipment (PPE)

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

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide,
registered under EPA Reg. No.
57223-2-4

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

- Sterilant 100X dilution, 11 hours 20°C
- Sporicidal 100X dilution, 11 hours 20°C
- Bactericidal 100X dilution, 11 hours 20°C
- Virucidal 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, 10 min., 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
- Pseudomonacidal
- 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

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- * **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 body 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:

1. **PERSONAL PROTECTION:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.
2. **CLEANING PROCEDURE:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the sterilant.
3. **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.
4. **CONTACT TIME:** Leave surfaces wet for 11 hours.

GENERAL DIRECTIONS FOR USE

1. It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.
2. **DO NOT USE AFTER EXPIRATION DATE.**
3. Do not allow Minncare® Cold Sterilant to mix with alkaline substances such as bleach (Sodium Hypochlorite).
4. If spilled, flush away with large quantities of water.
5. Use purified water when diluting Minncare® Cold Sterilant.
6. 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.

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DIRECTIONS FOR STERILIZATION

1. For use on hard, non-porous surfaces such as plastics, stainless steel objects or containers, glass used by laboratories, and manufacturers of pharmaceuticals, medical products, and cosmetics. Examples include glassware, laboratory instruments, containers, non-invasive dental/medical instruments such as forceps, scissors, clamps etc. This product is not to be used as a terminal sterilant on any critical/semi-critical medical device.
2. 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.
3. Dilute Minncare® Cold Sterilant 100X (1 part Minncare plus 99 parts purified water). Do not store diluted Minncare® Cold Sterilant for use as a sterilant; once diluted, use immediately.
4. Immerse the item to be sterilized in a sufficient volume of diluted Minncare® 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).
5. Remove items after 11 hours and rinse with sterile water until effluent testing shows acceptable levels when tested with Minncare® Residual Test Strips.
6. This product may be used to pre-clean or decontaminate critical/semi-critical medical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR HOSPITAL DISINFECTION

1. Minncare® Cold Sterilant is to be used on hard, non-porous surfaces such as plastic, glass, or stainless steel in settings such as hospitals, clinics, or physician's offices. Examples include counters, bed rails, bathroom fixtures, bedpans, non-invasive medical instruments (scissors, clamps) etc. This product is not to be used as a terminal high level disinfectant on any critical/semi-critical medical device.
2. 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.

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DIRECTIONS FOR HOSPITAL DISINFECTION Cont.

3. Dilute Minncare® Cold Sterilant 100X (1 part Minncare® 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 Minncare® Cold Sterilant to cover the item and fill all passages requiring disinfecting. Hold in the disinfecting solution for a minimum of 10 minutes.
4. Remove items after 10 minutes and rinse with sterile water until effluent shows acceptable levels when tested with Minncare® Residual Test Strips.
5. 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 either preceding or following regular cleaning and disinfecting procedures for hard room surfaces.

1. Prior to fogging, remove or carefully protect all food products and packaging materials.
2. Ensure room is properly ventilated. Vacate all personnel from the room during fogging and for a minimum of 2 hours after fogging or until the hydrogen peroxide air concentration is below 0.5 ppm.
3. Fog areas using one quart (946 ml) per 1000 cu. ft. (28.3 m3) of room volume with a 0.30 % Minncare solution.
4. 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

Minncare® 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. Minncare® 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. Minncare® Cold Sterilant should be used in a sanitation program, which includes bacteriological monitoring of the entire RO water system.

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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, Plexiglas, 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.

1. 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 with RO permeate.
2. Mineral deposits should be removed with an acidic cleaner prior to sanitizing of 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.
3. Prepare a 1% solution (1 part Minnicare® Cold Sterilant to 99 parts water) by adding the Minnicare® Cold Sterilant solution 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.

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4. Recirculate the 1% Minncare® Cold Sterilant solution until the entire system is filled.
5. Allow the elements to soak in the 1% Minncare® Cold Sterilant solution for a minimum of 36 minutes at 20°C (68°F).
6. 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

1. For use as a germicidal spray on hard surfaces such as floors, walls, bathroom fixtures, vinyl or Formica surfaces.
2. Dilute 100X with purified water. Note: Once diluted, the solution must be used within seven (7) days. Discard any unused diluted solution.
3. Spray onto surfaces using a plastic spray bottle.
4. Allow to remain on surface for 10 minutes.
5. 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)

1. 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.
2. Using water or mechanical action, remove heavy soil and gross filth from hard, non-porous surfaces such as Formica, stainless steel, or plastic.
3. 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.

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4. 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.
5. Rinse with purified water, drain excess, if possible, and allow to air dry.

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

1. 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.
2. 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.
3. Using an appropriate detergent or cleaner, wash surfaces or objects. Rinse with potable water.
4. Remove any food products or packaging materials from the room or cover completely.
5. 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.
6. Dip, spray, brush or fill equipment with solution and allow to sit at least 1 minute at 75°F(25°C).
7. 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

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STORAGE AND DISPOSAL

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

Pesticide Storage

1. Store in shipping carton.
2. Do not expose to direct sunlight.
3. Maintain temperature below 75°F (24°C).
4. Avoid contact with combustible materials.
5. 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.
6. Store in original closed container. NEVER TAMPER WITH VENT.

Pesticide Disposal

1. 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.
2. 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

Triple rinse empty container with water, then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill, incinerate, or, if allowed by state and local authorities, by burning. If burned, stay clear of the smoke.

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