

52252-4

10-05-2009

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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OCT 05 2009

Mr. Richard Ormsbee  
Corporate RA Manager for,  
Minntech Corporation  
14605 28<sup>th</sup> Avenue North  
Minneapolis, MN 55447

Subject: Minncare Cold Sterilant  
EPA Registration Number 52252-4  
Your Notification Dated September 22<sup>nd</sup>, 2009  
EPA Received Date September 24<sup>th</sup>, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add the additional brand name, ALTAcare Cold Sterilant, to delete the section entitled "Directions for Sanitizing of Reverse Osmosis Membranes", and to delete the section entitled, "Dispensing Minncare Cold Sterilant with Luer Lock Syringe" from the product labeling, is acceptable.

The notification has been part of the permanent record of this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink that reads "Marshall Swindell".

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



United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration  
 Amendment  
 Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 52252-4	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Minnicare Cold Sterilant	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Minntech Corporation 14605 28th Avenue North Minneapolis, MN 55447 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: <input checked="" type="checkbox"/> EPA Reg. No. _____ Product Name _____	

**Section - II**

Amendment - Explain below.  Final printed labels in response to Agency letter dated \_\_\_\_\_  
 Resubmission in response to Agency letter dated \_\_\_\_\_  "Me Too" Application.  
 Notification - Explain below.  Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Notification of alternate brand name. The alternate brand name is ALTAcare Cold Sterilant.

See addition page (1).

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Richard M. Ormsbee	Title Corporate RA Manager	Telephone No. (include Area Code) 763-551-2689
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. This Application Received (Stamped)
2. Signature 	3. Title Corporate Regulatory Affairs Manager	
4. Typed Name Richard M. Ormsbee	5. Date 22Sept2009	



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**ALTACARE® COLD STERILANT**  
**Master Label**

For the sterilization and disinfection of hard surfaces and non-porous food contact surfaces.

For use in the following locations;

- |                                     |                               |
|-------------------------------------|-------------------------------|
| Industrial Laboratories             | Hospitals (as a disinfectant) |
| 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 | Animal Hospitals              |
| Breweries/Wineries                  | Veterinary Clinics            |

Read the ALTAcare 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%

<b>Inert Ingredients</b>	<u>73.5%</u>
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<b>Total</b>	100.0%
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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 28 <sup>th</sup> 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	.....

**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.

<b>FIRST AID</b>	
<b>IF INHALED:</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for further treatment advice.</li> </ul>
<b>IF ON SKIN OR ON CLOTHING:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment.</li> </ul>
<b>IF IN EYES:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after first 5 minutes, then continue rinsing.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>IF SWALLOWED:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>HOT LINE NUMBER</b>	
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.	
<b>Note to Physician:</b>	
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

- 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

- \* **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:**

**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.

**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.

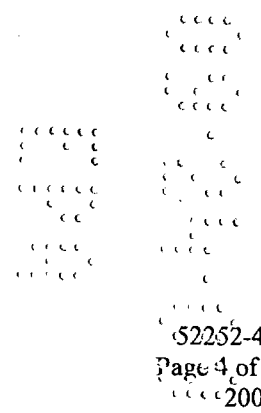
**GENERAL DIRECTIONS FOR USE**

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 ALTAcare 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 ALTAcare Cold Sterilant.

ALTAcare 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.

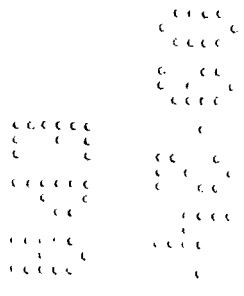


DIRECTIONS FOR STERILIZATION

ALTAcare Cold Sterilant may be used as a sterilant in any application other than a 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 ALTAcare Cold Sterilant 100X (1 part ALTAcare plus 99 parts purified water). Do not store diluted ALTAcare Cold Sterilant for use as a sterilant; once diluted, use immediately. Immerse the item to be sterilized in a sufficient volume of diluted ALTAcare 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 residual test strips.

DIRECTIONS FOR HOSPITAL DISINFECTION

ALTAcare 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. 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 ALTAcare Cold Sterilant 100X (1 part ALTAcare 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 ALTAcare 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 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 ALTAcare 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 ALTAcare 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 ALTAcare 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 USE AS A GERMICIDAL DISINFECTANT SPRAY

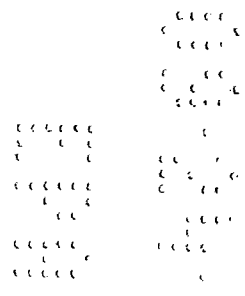
For use as a germicidal spray on hard surfaces such as floors, walls, bathroom fixtures, vinyl or Formica surfaces. Dilute 100X with purified water. Note: Once diluted, the solution must be used within seven (7) days. Discard any unused diluted solution. Spray onto surfaces using a plastic spray bottle. 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. ALTAcare 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)

ALTAcare 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 any food products or packaging materials from the room or cover completely. Dilute ALTAcare 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:

- 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 or 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

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.