52252-7 3/11/2009 1/14

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Mr. Richard M. Ormsbee
Senior Regulatory Affairs Specialist for,
Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447-4822

MAR 11 2009

Subject: Actril Cold Sterilant
EPA Registration Number 52252-7
Your Notification Dated February 14th, 2009
EPA Received Date February 17th, 2009

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add optional statements to 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,

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

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060 Print Form 3/14

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
52252-7	Marshall Swindell	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Minntech Corporation/ Actril COld Sterilant	Team #33	

5. Name and Address of Applicant *(Include ZIP Code)*

Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447

☐ *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:

EPA Reg. No. _____

Product Name _____

Section - II

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

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

Notification of Changes in Packaging and Related Labeling Statements per PR Notice 98-10.

See "Section II Additional Page".

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☐ Label ☐ Container		☐ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Richard M. Ormsbee	Senior RA Specialist	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. Date Application Received (Stamped)

2. Signature	3. Title
	Senior Regulatory Affairs Specialist
4. Typed Name	**5. Date**
Richard M. Ormsbee	14Feb2009

3/14

Section II Additional Page

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. 1001 to willfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action penalties under sections 12 and 14 of FIFRA.

4/14

MINNTECH®

Minntech Corporation
14605 28th Avenue North
Minneapolis, Minnesota 55447-4822 USA
Telephone: (763) 553-3300
FAX: (763) 553-3387

February 14, 2009

Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Re: Amendment to Minntech Corporation's Actril Cold Sterilant (EPA Registration #52252-7)

Minntech Corporation is submitting this notification for our Actril Cold Sterilant master label. The chemical formulation has not changed, and subsequently neither has the confidential statement of formula.

Accompanying the notification form, per PR Notice 98-10, is one copy of the proposed Actril Cold Sterilant master label with the changes on page 10 of 10 clearly marked.

If you have any questions, please call me at (763) 551-2689 or fax at (763) 553-3387.

Sincerely,

Richard M. Ormsbee
Senior Regulatory Affairs Specialist

ACTRIL® COLD STERILANT
Master Label

For Use In Health Care Environments

Active Ingredients

Hydrogen Peroxide	1.00%
Peroxyacetic Acid	.08%
Inert Ingredients	98.92%
Total	100.00%

EPA Reg. No. 52252-7

EPA Est. No. 52252-MN-01

Net Contents: _____

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See side panel for additional precautionary statements

Lot No. _____

Expiration Date: _____

(Minntech logo) MINNTECH

Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447 U.S.A.
Tel: (763) 553-3300
Toll Free: (800) 328-3340
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. 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	• 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	• 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	• 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	• 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.

(Applicable to volumes of 5 gallons or greater.)
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 CLAIMS

• Sterilant	undiluted 5½ hr.	20°C
• Sporicidal	undiluted 5½ hr.	20°C
• Bactericidal	undiluted 5½ hr.	20°C
• Virucidal	undiluted 5½ hr.	20°C
Hepatitis B	undiluted 5½ hr.	20°C
HIV-1*	undiluted 5½ hr.	20°C
• Fungicidal	undiluted 5½ hr.	20°C
• Broad Spectrum Disinfectant	undiluted 10 min.	20°C
• Hospital Disinfectant	Dilute 50X 10min.	20°C
and Pseudomonacidal	Use Fresh Solution Only,	Do Not Reuse
• Cleaner-Sanitizer	50X dilution	Do Not Reuse
(non-food contact surfaces)		
• Tuberculocidal	undiluted 10 min.	20°C
	Use Fresh Solution Only,	Do Not Reuse

- Non-Staining
- Pre-Activated/No Activation Needed
- Fast-Acting
- Reusable
  - As a sterilant for 14 days
  - As a broad spectrum disinfectant for 14 days (when used undiluted)
- Germicidal Spray Disinfectant undiluted 30 sec. 20°C

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

* 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 inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV-1 (Human Immunodeficiency Virus Type 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 the 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 with undiluted Actril Cold Sterilant for a minimum of 5½ hours

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 Actril Cold Sterilant to mix with alkaline substances such as bleach (Sodium hypochlorite) or other oxidizing agents.
4. Use purified water (e.g. deionized) for making dilutions, cleaning and rinsing.
5. Some materials may be incompatible with Actril Cold Sterilant. Test material prior to use.
6. Reuse of diluted Actril Cold Sterilant is not recommended.

DIRECTIONS FOR STERILIZATION

1. Actril Cold Sterilant may be used to sterilize non-invasive dental/surgical equipment such as pressure clamps, tubing clamps, blood pressure cuffs, mirrors 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 water or by detergent cleaning followed by a water rinse.

3. Immerse the item to be sterilized in a sufficient volume of undiluted Actril Cold Sterilant to cover the item and fill all passages requiring sterilization. Hold in sterilizing solution for a minimum of 5½ hours at 20°C temperature (68°F).

4. Remove items after 5½ hours and rinse with sterile water until rinse water shows level of 10 ppm or less when tested with Actril Residual Test Strips.

5. The solution may be used and reused for up to 14 days in a manual system with 5½ hours immersion.

DIRECTIONS FOR BROAD SPECTRUM DISINFECTION

1. For broad spectrum disinfection of items such as external surfaces of medical equipment, kidney dialysis machines, non-invasive dental instruments, counters, bathroom fixtures, 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 (e.g. deionized), mechanical action, or by detergent cleaning followed by a water rinse.

3. Immerse the item to be disinfected in sufficient volume of undiluted Actril Cold Sterilant solution to cover the item and/or where appropriate by filling all passages requiring disinfection. Hold item in contact with the disinfecting solution for a minimum of 10 minutes at 20°C temperature (68°F).

4. Remove items after 10 minutes and rinse with purified water until effluent shows acceptable levels when tested with Actril Residual Test Strips.

5. The solution may be used and reused for up to 14 days in a manual system with 10 minutes immersion.

6. For tuberculocidal activity at 20°C with fresh, undiluted solution, immerse completely for 10 minutes. Remove items and rinse thoroughly.

7. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

DIRECTIONS FOR HOSPITAL DISINFECTION

1. For disinfection of items such as external surfaces of medical equipment, counters, bathroom fixtures, 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 or by detergent cleaning followed by a water rinse.

3. Immerse the pre-cleaned item to be disinfected in sufficient volume of freshly diluted 50X Actril Cold Sterilant using purified water, to cover the item and fill all passages requiring disinfection. Hold item in contact with the disinfecting solution for a minimum of 10 minutes at 20°C temperature (68°F).

4. Remove items after 10 minutes and rinse with purified water until rinse water shows levels of 10 ppm or less when tested with Actril Residual Test Strips.

5. Cannot be reused as a hospital disinfectant.

6. This product may be used to pre-clean or decontaminate critical or 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 undiluted Actril solution.

4. Allow surfaces to dry thoroughly before operations are resumed.

Note: In all applications, always prepare a new solution daily to ensure effectiveness. Do not reuse solutions. Dispose of any unused solution.

Directions for Use in the AxSYM/AxSYM Plus Instrument

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

This product is to be used only for cleaning and inhibition of fouling bacteria in the AxSYM/AxSYM Plus tubing system of their in-vitro immunoassay analyzer.

For (*in vitro*) diagnostic use only.

For use in the AxSYM SYSTEM for Monthly Maintenance of Tubing Decontamination.

Perform the procedure found in the AxSYM SYSTEM Operations Manual, Section 9: Service and Maintenance. In accordance with the Operations Manual perform the following:

1. Prepare a 5% solution by diluting 20 ml into 380 ml of approved water. Note: The dilution solution is to be used immediately.
2. Empty the Liquid Waste Container and update Liquid Waste Inventory.
3. Select MAINTENANCE from the Main Menu screen.
4. Select TUBING DECONTAMINATION.
5. Select OK and allow the system to run for the entire cycle.
6. Rinse and flush with water per directions on the Tubing Decontamination Rinse screen.

Directions for Use as a Germicidal Disinfectant Spray

1. Spray Actril Cold Sterilant undiluted onto cleaned surface using a plastic spray bottle.
2. Allow to remain on surface for 30 seconds.
3. 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 (Non-food contact surfaces)

1. Using water or mechanical action, remove heavy soil or gross filth from hard surfaces such as Formica, stainless steel or vinyl surfaces.
2. Apply by cloth, mop or sponge so as to wet all surfaces thoroughly, a freshly made 50X dilution of Actril Cold Sterilant, made using purified water, to the pre-cleaned surface or immerse pre-cleaned items to be sanitized in the solution. Allow 5 minutes of contact time. Let air dry or rinse with purified water, drain excess if possible and allow to air dry.
3. May NOT be reused as a cleaner/sanitizer.

USES

Primarily intended for sterilization, disinfection or sanitization of:

- Stainless Steel
- Plastic Items and surfaces
- Anesthesia Equipment
- Medical Equipment
- External Surfaces of Respiratory Equipment
- Hard Surfaces e.g. counter tops
- Non-Invasive Surgical Equipment
- Floors
- Walls
- Bathroom fixtures
- Glass
- Non-Invasive Dental Instruments
- Formica
- Vinyl

Materials Compatibility: Polyvinyl chloride, polypropylene, polyurethane, aceto-copolymers, polycarbonate, polysulfone, polystyrene, stainless steel.

STORAGE AND DISPOSAL

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

Pesticide Storage

1. Store upright 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. Store in original closed container.
6. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (703) 527-3387.

Pesticide Disposal

Wastes resulting from the use of this product may be disposed of on-site 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, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{Optional Statements}

Packaged in Clean Room Conditions
6 x 1 liter
6 x 0.96 liter
Packaged with Sprayheads
Double Bagged
ETO Exposed Packaging
ETO Processed Packaging
Ethylene Oxide Exposed Packaging
Ethylene Oxide Processed Packaging