

52252-7

6/21/2007



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447

JUN 21 2007

Attention: Richard M. Ormsbee
Regulatory Manager

Subject: Actril Cold Sterilant
EPA Reg. No. 52252-7
Amendment Dated April 18, 2007

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable provided the following label revisions are inserted:

1. On page 7g of the master label, the misuse statement "It is a violation of . . . inconsistent with its labeling . . ." needs to move from the second statement, to the first, immediately below the "Directions for Use" heading.
2. On page 7g of the master label, change "AxSYM's tubing system" to "AxSYM/AxSYM Plus tubing system of their in vitro immunoassay analyzer."
3. On the proposed "Tubing Decontamination* Solution" label delete the "*" from the product name. Also delete the asterisk from the first sentence of the use directions section on the master label (page 7g) and the proposed label.

It is the Agency's understanding that the claim for decontaminating the tubing of the "AxSYM/AxSYM Plus" in vitro immunoassay analyzer will only be marketed on an additional brand name label, and or supplemental distributor label containing no other pesticidal claims. We note that you provided a sample label for our review. The Agency has no objections to the content of the additional brand name label provided that the labeling comments included in this letter are incorporated in the labeling as well as the master label. In the interest of this amendment, the master label has been stamped for approval with comments. The Agency does not stamp accepted additional brand name labels.

In conjunction with this labeling amendment request the Agency is also accepting the name AxSYM System Tubing Decontamination Solution" as an additional brand name for this registration.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,

M. Swindell
o/p for Marshall Swindell

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

ACTRIL® COLD STERILANT
Master Label

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For Use In Health Care Environments

Active Ingredients

Hydrogen Peroxide 1.00%
Peroxyacetic Acid08%

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

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ACCEPTED
ACCEPTED COMMENTS
with COMMENTS
in EPA Letter Dated
JUN 21 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the use as a
registered under EPA Reg. No
52252-7

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PRECAUTIONARY STATEMENTS

Hazards 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 | <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. | |

ACCEPTED
with COMMENTS
in EPA Letter Label

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

Actrial Cold Sterilant Master Label

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07a

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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.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide, registered under EPA Reg. No. 52252-7
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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.

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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.

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Actril Cold Sterilant Master Label Registered under EPA Reg. No.

52252-7e
07a

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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.

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Directions for Use in the AxSYM/AxSYM Plus Instrument

This product is to be used only for cleaning and inhibition of fouling bacteria in the ~~AxSYM tubing system~~. This product does not disinfect or sterilize the tubing system. AxSYM/AxSYM Plus tubing system of their in vitro immunoassay analyzer
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

For (*in vitro*) diagnostic use only.

For use in the AxSYM/AxSYM Plus SYSTEM for monthly maintenance of tubing.

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 diluted 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.

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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

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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.

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