

NOTICE OF PESTICIDE: REGISTRATION
 REREISTRATION

(Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Actrl Cold Sterilant For
Dialysis Use

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Minntech Corporation
14905 23th Avenue North
Minneapolis, MN 55447

NOTE: Changes in labeling formula 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 U.S. 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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this 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.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. Make the labeling changes listed below before you release the product for shipment:

- a. Add the phrase "EPA Registration No. 52252-3."
- b. Revise (3.7^g liter) to read (3.7^l liters).
- c. Provide Use Directions for disinfection of "Reverse Osmosis (RO) Water Systems and Associated Distribution Systems" directly on the label
- d. Revise HIV to read HIV-1.
- e. Refer to *Federal Register* for appropriate labeling statements for the HIV-1 claim.

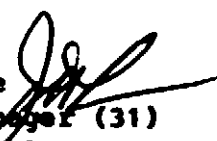
ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL

DATE

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 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.

John H. Lee 
Product Manager (31)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

S&P 15

ACTRIL™ COLD STERILANT

FOR DIALYSIS USE

**For Use In Environments Administering Dialysis Care
Including RO Membranes and Their Associated Water
Distribution Systems.**

Active Ingredients

Hydrogen Peroxide 0.80%
Peroxyacetic Acid 0.06%

Inert Ingredients 99.14%

Total 100.00%

Net Contents: 1 U.S. gallon (3.78 liter)

KEEP OUT OF REACH OF CHILDREN

DANGER

See side panel for additional precautionary statements

EPA Reg. No.:

EPA Est. No.: 52252-MN-01

Lot No. _____

Expiration Date: _____

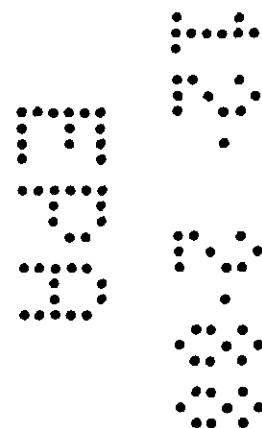
ACCEPTED
WITH COMMENTS
By EPA Region 5 Office

MAR 09 1990

S 2252-3

(RSI logo) RENAL
SYSTEMS

Division of Minntech Corporation
14905 28th Avenue North
Minneapolis, Minnesota 55447 U.S.A.
Telephone (612) 553-3300
(800) 328-3340
Telex 29-0825 RSIMPLS PLOH

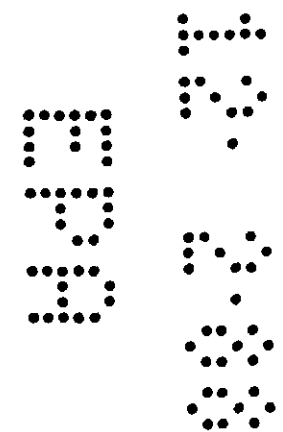


4675

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 undiluted 5½ hr. 20°C
- Fungicidal undiluted 5½ hr. 20°C
- Broad Spectrum Disinfectant undiluted 10 min. 20°C
- Hospital Disinfectant Diluted 50X 10 min. 20°C
 - Pseudomonacidal Use Fresh Solution
 - Do Not Reuse
- Cleaner-Sanitizer (non-food contact surfaces) 50X dilution
 - Do Not Reuse
- Tuberculocidal 10 min. 20°C Use Fresh Solution Only
- Non-Staining
- Pre-Activated/No Activation Needed
- Fast-Acting
- Reusable
 - As a sterilant for 30 days
 - As a broad spectrum disinfectant for 30 days (when used undiluted)
- Germicidal Spray Disinfectant undiluted 30 sec. 20°C
- Kidney machine disinfectant

ACCEPTED
 WITH COMMENTS
 in EPA 7-1-1
 52252-3
 MAR 00 1990



PRECAUTIONARY STATEMENTS

Hazard to humans and domestic animals.

Eyes: Corrosive, causes eye damage.
Do not get in eyes. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly after handling.

Statement of Practical Treatment

In case of contact with eyes, flush with large amounts of water for at least fifteen (15) minutes. Get prompt medical attention.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED
with COMMENTS
in EPA...

MAR 09 1990

50050-3

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™ to mix with alkaline substances such as bleach (Sodium hypochlorite) or other oxidizing agents.
- 4) Use AAMI Quality Water for Hemodialysis in making dilutions.
- 5) Some materials may be incompatible with Actril™. Read package insert regarding material compatibility.
- 6) Reuse of diluted Actril™ is not recommended.

.....

DIRECTIONS FOR BROAD SPECTRUM DISINFECTION

1. For broad spectrum disinfection of items such as plastic dialyzer caps, 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.
2. 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).
3. Remove items after 10 minutes and rinse with purified water until effluent shows acceptable levels when tested with Actril™ Residual Test Strips. If cap is to be used on a dialyzer, DO NOT rinse. Place directly onto dialyzer.
4. The solution may be used and reused for up to 30 days in a manual system with 10 minutes immersion.
5. For tuberculocidal activity at 20°C with unused solution, immerse completely for 10 minutes. Remove items and rinse thoroughly.

DIRECTIONS FOR STERILIZATION

1. Remove any obvious debris or organic material from the surface to be sterilized. This can often be accomplished by rinsing with AAMI Quality Water for Hemodialysis or by detergent cleaning followed by a water rinse.
2. 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 the sterilizing solution for a minimum of 5½ hours at a temperature of 20°C (68°F).
3. Remove items after 5½ hours and rinse with sterile water until rinse water shows levels of 10 ppm or less when tested with Actril™ Residual Test Strips.
4. The solution may be used and reused for up to 30 days in a manual system with 5½ hours immersion.

ACCEPTED
NO COMMENTS
JUL 11 1990

MAY 10 1990

52255-2

DIRECTIONS FOR HOSPITAL DISINFECTION

1. Remove any obvious debris or organic material from the surface to be disinfected. This can often be accomplished by rinsing with water (e.g. AAMI Water for Hemodialysis) or by detergent cleaning followed by a water rinse.
2. Immerse the item to be disinfected in sufficient volume of freshly made 50X diluted Actril™ Cold Sterilant made using quality water (eg., AAMI Water for Hemodialysis) to cover the item and fill all passages requiring disinfection. Hold in the disinfecting solution for a minimum of 10 minutes.
3. Remove items after 10 minutes and rinse with sterile water until rinse water shows levels of 10 ppm or less when tested with Actril™ Residual Test Strips.
4. May not be reused as a hospital disinfectant.
5. For tuberculocidal activity at 20°C with unused solution immerse completely for 10 minutes. Remove items and rinse thoroughly.

**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 plastic surface.
2. Apply a freshly made 50X dilution of Actril™, made using purified water, to the surface or immerse 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. Product may be applied by cloth, mop or sponge.
4. May not be reused as a cleaner sanitizer.

ACCEPTED
with COMMENTS
in EPA 1-19-89

MAR 09 1990

3-25-89



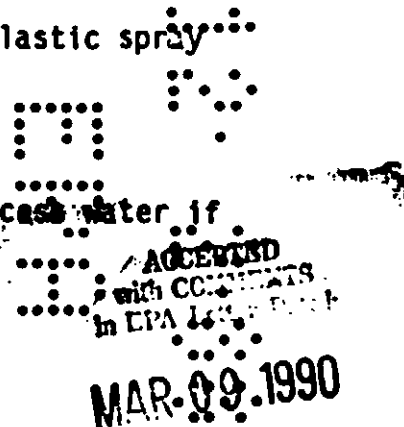
KIDNEY MACHINE DISINFECTION

General directions for use are listed below. Directions for specific dialysis machines are given in the package insert.

1. Use undiluted Actril™ to disinfect the concentrate/dialysate pathway. The machine will proportion and dilute Actril™ (35X or 44X) for proper disinfection. Use Actril™ Indicator Test Strips at the drain discharge to ensure fill of the machine. Consult package insert for the volumes and dwell times required for each specific dialysis machine.
2. Use the appropriate dilution of Actril™ to disinfect the water inlet path of the dialysis machine. Use of this higher concentration through the water line allows disinfection of the entire system including the water supply lines. Use Actril™ Indicator Test Strips at the drain discharge to ensure that the machine has been filled with disinfectant. Consult package insert for the dilution levels, volumes and dwell times required for each specific dialysis machine.
3. After the appropriate dwell time of Actril™ in the machine, rinse the machine with AAMI Quality Water, following directions. Test drain effluent with Actril™ Residual Test Strips to ensure complete rinse of the machine to a maximum of 10 ppm.
4. Actril™ Solution is recommended for decontaminating single patient and multipatient hemodialysis delivery systems. It is an effective disinfectant. However, Actril™ Solution may not totally eliminate all vegetative microorganisms in hemodialysate delivery systems due to their construction and/or assembly and the possibility of recontamination by the incoming water. Actril™ used according to the directions will reduce the number of microorganisms to an acceptable level. Actril™ should be used in a disinfection program which includes bacteriological monitoring of the entire hemodialysate delivery system.

Directions for Use as a Germicidal Spray

1. Spray Actril™ 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.



USES

Primarily intended for sterilization or disinfection of:

Dialysis Equipment
 Hard Surfaces
 Surgical Instruments
 Plastic Objects

Machine Exteriors
 Floors
 Counter Surfaces
 Reverse Osmosis (RO) Water Systems and
 Associated Distribution System

50223

STORAGE AND DISPOSAL

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.
6. Store in original closed container.
7. For chemical emergency, spill, leak, fire, exposure and accident, call Chemtrec, day or night (800) 424-9300, (202) 483-7616.

Pesticide Disposal

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

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 dispose of by burning. If burned, stay clear of the smoke.

ACCEPTED
 WITH COMMENTS
 in EPA Lab

MAR 09 1980

5252-3

PACKAGE INSERT

On the following pages is a copy of the package insert which will be included in each case of 4 one-gallon bottles of Actril™ Cold Sterilant.

This package insert gives directions to using the product to disinfect kidney dialysis machines from various manufacturers.

To be Added

Directions For Use:

"It is a Violation of Federal law to use this product in a manner Inconsistent with its labeling."

ACCEPTED
with COMMENTS
in 1990

MAR 09 1990

50152-3
[Barcode]

Renal Systems
Division of Minotech Corporation

APR 09 1990
555523

ACCEPTED

Actril T.M.

WORLD STERILANT

Read this Package Insert and Actril label prior to use

ACTRIL™ PACKAGE INSERT
for Kidney Machine Disinfection

PA Reg No

Individual Procedures

The following procedures are for these kidney dialysis machines: Travnel SPS450, Gambro AK-10, Drake Willock 4215, and Cobe Centry 7 Rx. There are two procedures for each machine.

The first procedure is used as a routine disinfection procedure (i.e. daily or following each use). These are headed "Routine Disinfection." By following these instructions on a routine basis, the microbial contamination in the system can be controlled. The exposure time is short and the concentrate is drawn directly into the concentrate line, making this a simple convenient way to routinely disinfect the concentrate and dialysate portions of the fluid pathway.

The second procedure will provide a higher level of disinfection and is headed "Highest Level Disinfection." This procedure should be used when contamination of the entire machine is suspected. This procedure requires a 12 hour exposure and a higher (less dilute) concentration of Actril™. The Actril™ is introduced into the machine through the water line and provides disinfection for the entire fluid pathway, including the water supply line.

This highest level of disinfection would normally be used after prolonged storage of the machine, when the machine was exposed to abnormally high levels of contamination, or when the water supply had failed and contamination entered the machine through the water supply line.

When using Actril™, the appropriate test kits should be used to ensure that the solution is passed through the entire machine and that the solution is rinsed from the machine. When testing for the presence of Actril™ in the machine, the indicator test strip should be placed into the drain effluent. If the test indicates too low a concentration, the disinfection procedure should be repeated from the beginning. When testing for residual Actril™ following rinsing of the machine, the test strip should be placed in the drain effluent and the machine not used until a reading of less than 3ppm is obtained.

Travnel SPS450 Routine Disinfection (Concentrate and Dialysate Paths)

NOTE: This procedure corresponds to the "Disinfect Dialysate Path" procedure on page 2-2 of the TRAVNEL Operator's Manual (1157-1235-999 2/86), and page 6 of Operator's Manual Supplement Bicarbonate Retrofit Kit for single patient systems (1157-1214-981 3/86). This disinfection procedure with Actril™ Solution may also remove calcium and magnesium precipitates which result from bicarbonate dialysis, eliminating the vinegar rinse procedure recommended by the manufacturer. (See publication 1157-1214-981, 3/86, page 6)

The dialysate path of the SPS450 must be disinfected before every dialysis. The concentrate/rinse line is used to draw disinfectant into the dialysate path. On machines with a bicarbonate dialysate feature, the bicarbonate concentrate line is used in addition to the concentrate/rinse line (the concentrate/rinse line is called the "acid/acetate concentrate line" on bicarbonate machines). Actril™ Solution is used as the disinfectant.

1. Measure 200 milliliters of Actril™ Solution into a suitable container.

Also apply to Disinfection of the Water System including the water supply lines.

2. Connect both dialysate hoses to the interlock parts. The female quick-disconnect fittings must slide all the way on to the two male fittings. Both fittings are correctly connected when the rocker arm push in and activate the interlock.
3. Connect the concentrate/rinse line to the water rinse port. Plug in the SPS450 and turn on the water supply. Use RO or equivalent AAMI Quality Water for Hemodialysis.
4. Switch to normalize/disinfect for at least 6 minutes to rinse the SPS450. A water rinse is necessary before disinfecting to completely clear the system of dialysate.
5. Disconnect the concentrate/rinse line from the water rinse port and put the line into the container of Actril™ Solution. If there is a bicarbonate concentrate line, place that in the disinfectant as well. Allow all of the disinfectant to be drawn into the SPS450. This should take about 7 minutes for a bicarbonate machine or about 15 minutes for an acetate machine.
6. Perform a test to verify that the machine contains the disinfectant using Renal Systems Actril™ Indicator Test Strips. Dip the Test Strip directly into a sample from the drain hose. If the strip turns dark blue, sufficient disinfectant is present.
7. Turn the SPS450 off for 30 minutes to allow the disinfectant to dwell in the machine. Reconnect the concentrate/rinse and the bicarbonate lines to their rinse ports. CAUTION: As a precaution, tag the SPS450 whenever it is filled with disinfectant.
8. Following the 30 minute dwell time, turn the machine on. Switch the SPS450 to normalize/disinfect for 20 minutes to clear all of the disinfectant from the system.
9. Test for residual disinfectant by sampling fluid at the dialysate sampling port. Perform the test using Actril™ Residual Test Strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, rinse for another 10 minutes and test again. Continue rinsing until the test shows an acceptable level.
10. Proceed to the "Normalize" instructions on page 2-3 of the TRAVNEL Operator's Manual.

Travnel SPS450 Highest Level Disinfection (Concentrate, Dialysate and Water Paths)

NOTE: This procedure corresponds to the procedure on page 4-36 of the TRAVNEL Operator's Manual for "Disinfecting the Incoming Water Path" of the Travnel SPS450.

The incoming water path up through the proportioning pump must be disinfected whenever the water supply or SPS450 fluid path show total viable microbial counts above acceptable standards for hemodialysis water. Disconnect the SPS450 from the water supply before disinfecting the incoming water path. Consult your water treatment specialist for directions for disinfecting your water supply. Do not reconnect the SPS450 unless the water meets acceptable standards.

1. Water-rinse the SPS450 in normalize/disinfect for 10 minutes. Use AAMI Quality Water for Hemodialysis.
2. Prepare a 3:1 dilution of the disinfectant in a suitable 3 liter container. Mix 1 liter of Actril™ Solution with 2 liters of AAMI Quality Water.
3. Turn the SPS450 off, unplug it, and turn off the water.
4. Take a control sample from the water supply and culture it for bacteria.

5. Remove filter
6. Insert tube into filter
7. Fill dilution house
8. Connect pump to pressure
9. Disconnect water line into infection
10. Plug disinfectant
11. With IMP draw the SPS450
12. Perform control system the blue press
13. Remove filter
14. Turn the CAUTION when
15. After empty AAMI Refill and
16. Record water the information
17. Test fluid test result
18. Show Swab (with use Cult for sh. take
19. Turn the
20. Name tube house
21. After the time

Gambro / Routine (Concentrate)

NOTE:

Disinfection and cleaning section of the Operator's Manual for Bicarbonate Monitor BCM 10-1 (JHC-841W).

Before initiating the Chemical disinfection mode:

1. Depress ALARM BYPASS (light will turn on).
2. Release TMP ON (the light will turn off).
3. Check that the dialysate lines are connected to the safety bypass couplings.
4. Check that the AK-10 concentrate pick-up tube (C) is in the heating vessel of the ...
5. Check that the BCM concentrate pick-up tubes (A & B) are locked in the disinfection position in the BCM-10.
6. Press CHEM.DISINF. (light on), then immediately press DRAIN (light on). Use AAMI quality water for hemodialysis to rinse. Release MAIN SWITCH (light off) to reset the program.

Chemical disinfection

1. Prepare 2 liters of disinfectant solution by diluting 200 milliliters of Actril[®] Solution with 1800 milliliters of AAMI Quality Water.
2. Remove the AK-10 concentrate pick-up tube (C) from the heating vessel and insert it into the container of prepared disinfectant solution.
3. Press MAIN SWITCH (light on). Press CHEM.DISINF. (light will turn on). The BCM ON light will also be lit. When the machine has been filled with disinfectant solution, the CHEM.DISINF. light will begin to blink.
4. Perform a test to verify that the machine contains the disinfectant using Renal Systems Actril[®] Indicator Test Strips. Dip the Test Strip into a sample from the Drain Hose. If the strip turns dark blue or black, sufficient disinfectant is present.
5. Place the concentrate pick-up tube in the heating vessel.
6. CAUTION: As a precaution, tag the machine whenever it is filled with disinfectant.
7. Press CHEM.DISINF. (the light will stop blinking and glow steadily). After about 20 minutes the DRAIN button will light. After two rinses and two drains the CHEM.DISINF. light will go out. The DRAIN light will remain on indicating the third and final drain.
8. Take a sample from the Drain Hose and perform a residual test using Actril[®] Residual Test Strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, follow the rinse procedure on page 2) of the Drake Willock 4215 Operator's Manual for hemodialysis and sequential dialysis and test again. Repeat the rinse procedure until acceptable residual levels are reached.
9. When the residual levels are acceptable and the DRAIN light begins to blink, release the MAIN SWITCH (the light will turn off).
10. Turn off the water supply.

NOTE: In order to disinfect the UF fluid path, refer to the machine Operator's Manual. Additional Actril[®] solutions will be required.

Drake Willock 4215 Higher Level Disinfection (Concentrate, Dialysate and Water Paths)

NOTE: The water path must be disinfected whenever the water supply or machine fluid path show total viable microbial counts above acceptable standards for hemodialysis water. This procedure uses

Actril[®] Solution corresponds to the "Chemical Disinfection" procedure on page 22 of the Drake AK-10 System Operator's Manual for Hemodialysis and Sequential Dialysis (JHC-4801), and the Disinfection and Cleaning section of the Operator's Manual for Bicarbonate Monitor BCM 10-1 (JHC-841W).

Before initiating the Chemical disinfection mode:

1. Depress ALARM BYPASS (light will turn on).
2. Release TMP ON (the light will turn off).
3. Check that the dialysate lines are connected to the safety bypass couplings.
4. Check that the AK-10 concentrate pick-up tube (C) is in the heating vessel of the AK-10.
5. Check that the BCM concentrate pick-up tubes (A & B) are locked in the disinfection position in the BCM-10.
6. Press CHEM.DISINF. (light on), then immediately press DRAIN (light on). Use AAMI quality water for hemodialysis to rinse. Release MAIN SWITCH (light off) to reset the program.

Chemical disinfection

1. Prepare two (2) liters of disinfectant solution by diluting one (1) liter of Actril[®] Solution with one (1) liter of AAMI Quality Water.
2. Remove the water filter from the incoming water filter housing. Empty the housing and measure 600 milliliters of the 2 liters of disinfectant solution into the housing. Add AAMI Quality Water (approximately 400 ml) to fill the filter housing to approximately three-fourths full.
3. Insert a filter housing insert tube (RS P/N 67735-000) into the filter housing in place of the filter to allow proper fluid displacement in the housing. Reconnect the filter housing.
4. Remove the AK-10 concentrate pick-up tube (C) from the heating vessel and insert it into the container with the remaining disinfectant solution (about 1400 milliliters).
5. Press CHEM.DISINF. (the light will turn on). The BCM ON light will also be lit. When the machine has been filled with disinfectant solution, the CHEM.DISINF. light will begin to blink.
6. Perform a test to verify that the machine contains the disinfectant using Renal Systems Actril[®] Indicator Test Strips. Dip the Test Strip into a sample from the Drain Hose. If the strip turns dark blue, sufficient disinfectant is present.
7. Place the concentrate pick-up tube in the heating vessel.
8. CAUTION: As a precaution, tag the machine whenever it is filled with disinfectant.
9. Release MAIN SWITCH (light off). Turn off water supply. Wait a minimum of 12 hours.
10. Turn on water supply. Press MAIN SWITCH (light on). Press CHEM.DISINF. When CHEM.DISINF. is lit, press DRAIN until lit. Machine will now be in RINSE mode. After about 20 minutes the DRAIN button will light. After two rinses and two drains the CHEM.DISINF. light will go out. The DRAIN light will remain on indicating the third and final drain.

NOTE: In order to disinfect the UF fluid path, refer to the machine Operator's Manual. Additional Actril[®] solutions will be required.

12. When the residual levels are acceptable and the DRAIN light begins to blink, release the MAIN SWITCH (the light will turn off).
13. Turn off the water supply.

NOTE: In order to disinfect the UF fluid path, refer to the machine Operator's Manual. An additional volume of 50% Actril[®] solution (2X dilution) will be required. Do not overdilute.

Drake Willock 4215 Routine Disinfection (Concentrate and Dialysate Paths)

NOTE: This procedure for disinfecting the dialysate path of the Drake Willock 4215 with Actril[®] Solution corresponds to the "Disinfect" procedure on page 19-2 of the Drake Willock 4215 Operator's Manual (PL-2200-40-1). The machine should be disinfected before the first use, after each use, and after replacing any component.

1. Rinse the machine with AAMI Quality Water for hemodialysis for 12 minutes. (Operator's Manual page 19-1) Disconnect the CONCENTRATE line from the rinse fitting and the BICARBONATE line (if applicable) from the recirculation fitting.
2. Drop the CONCENTRATE line and the BICARBONATE line into a container with 200 milliliters of Actril[®] Solution.
3. Uptake all of the solution from the container. (This should take 3-5 minutes with a bicarbonate-equipped machine and 10-12 minutes with an acetate machine.)
4. Perform a test to verify that the machine contains sufficient disinfectant using Actril[®] Indicator Test Strips. Take a sample from line number 16 (see Figure 1-2, page 1-4 Operator's Manual) at the dialyzer hookup assembly on the IV pole. If the strip turns dark blue or black sufficient disinfectant is present.
5. Turn the POWER switch OFF. Turn water off.
6. Tag the machine to indicate the presence of disinfectant. Allow the Actril[®] Solution to remain in the system until the next use, but a minimum of 30 minutes.
7. Remove the CONCENTRATE line from the disinfectant container and place it on the rinse fitting on the water manifold. Remove the BICARBONATE line from the disinfectant container and place it on the recirculation fitting.
8. Before the next use, rinse the system (with CANISTER/REC. PRESS. switch ON) with AAMI Quality Water for approximately 30 minutes. Test for residual disinfectant by sampling the fluid from line number 16 at the dialyzer hookup assembly on the IV pole. Perform the test using Actril[®] Residual Test Strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, continue rinsing until the level is acceptable.

Drake Willock 4215 Higher Level Disinfection (Water, Concentrate and Dialysate Paths)

NOTE: This procedure for cleaning and disinfecting the Drake Willock 4215 with Actril[®] Solution corresponds to the "Clean" procedure on page 19-3 of the Drake Willock 4215 Operator's Manual (PL-2200-40-1). The machine should be cleaned at least every month or 100 hours, whichever comes first.

1. Rinse the machine with AAMI Quality Water for hemodialysis for 12 minutes. (Operator's Manual page 19-2.) Turn machine off.

2. Prepare 1400 milliliters of disinfectant solution by mixing 700 milliliters of Actril[®] Solution with 700 milliliters of AAMI Quality Water.
3. Remove the water filter from the water filter housing and insert the filter housing insert tube (RS P/N 67735-000) into the filter housing to allow proper fluid displacement in the housing. Fill the housing with 1 liter of disinfectant solution, then reconnect the filter housing.
4. Disconnect the CONCENTRATE line from the rinse fitting and the BICARBONATE line (if applicable) from the recirculation fitting. Drop the CONCENTRATE line and the BICARBONATE line into a container holding the remaining disinfectant solution (about 400 milliliters).
5. Uptake the disinfectant for 5 minutes or until it is all taken up, whichever is less. IMPORTANT: NEVER EXCEED 5 MINUTES AS THIS WILL COMPROMISE DISINFECTION.
6. Perform a test to verify that the machine contains sufficient disinfectant solution using Renal Systems Actril[®] Indicator Test Strips. Take a sample from line number 16 (see Figure 1-2 of the Drake Willock 4215 Operator's Manual) at the dialyzer hookup assembly on the IV pole. If the strip turns dark blue or black, sufficient disinfectant is present.
7. Turn the POWER switch OFF. Turn water off.
8. Remove the CONCENTRATE line from the disinfectant container and place it on the rinse fitting on the water manifold. Remove the BICARBONATE line from the disinfectant container and place it on the recirculation fitting.
9. Allow the disinfectant to remain in the machine at least 12 hours. CAUTION: Tag the machine to indicate the presence of disinfectant.
10. After a minimum 12 hour dwell time, remove and empty the filter housing. Rinse it with AAMI quality water (2 complete exchanges). Refill the housing with AAMI quality water and replace the housing. Then rinse the system (WITH CANISTER/REC. PRESS. switch ON) with AAMI quality water for approximately 30 minutes.
11. Test for residual disinfectant by sampling the fluid from line number 16 at the dialyzer hookup assembly on the IV pole. Perform the test using Actril[®] Residual Test Strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, continue rinsing until the level is acceptable.

COE Centry 2 Rn Dialysis Control Unit Routine Disinfection (Concentrate and Dialysate Paths)

NOTE: This procedure for routine disinfection of the COE Centry 2 Rn Dialysis Control Unit with Actril[®] Solution corresponds to the "Cleaning" procedure on Page 3-23 of the COE Operator's Handbook (J435126-001 Rev. A). Use AAMI Quality Water for hemodialysis whenever water is required.

1. Connect the concentrate lines (ACETATE, ACID and BICARBONATE) to their Rinse Ports. Turn water supply on. Press RINSE button on. Allow five minutes for concentrate to rinse from the lines. Verify that fluid is present in all three concentrate lines.
2. Measure 700 milliliters of Actril[®] Solution into a suitable container.
3. Place the BICARBONATE CONCENTRATE line into the container of Actril[®] Solution.
4. Allow the machine to run until all of the disinfectant has been drawn into the concentrate line (approximately 4 minutes).

MAR 09 1990

12815

5. Perform a test to verify that the machine contains disinfectant using Renal Systems Actril[®] Solution Indicator Test Strips. Dip the Test Strip into a sample from the Drain Hose. If the strip turns dark blue or black, sufficient disinfectant is present.
6. Connect the BICARBONATE CONCENTRATE line to its Rinse port.
7. Press the RINSE button off.
8. Press the POWER switch OFF.
9. Turn the water supply off.
10. Allow the Actril[®] Solution to dwell in the machine for 30 minutes. NAME A DISINFECTANT TAG ON THE FRONT OF THE MACHINE. The tag serves as a warning that the machine contains a disinfectant solution.
11. Following a minimum 30 minute dwell time, turn the water supply on.
12. Press the POWER switch ON.
13. Press the RINSE button on. Allow the machine to rinse for 10-15 minutes.
14. Take a sample from the Drain Hose and perform a residual test using Actril[®] Residual Test strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, verify that the RINSE button is on, then continue rinsing until an acceptable level is indicated.
15. Press the RINSE button off.
16. Remove the DISINFECTANT tag and keep it for future use.
17. Press the POWER switch OFF.
18. Turn the water supply off.

COGE Entry 2Rx Dialysis Control Unit
Higher Level Disinfection
 (Concentrate, Dialysate and Water Paths)

NOTE: This procedure for disinfecting the COGE Entry 2 Rx Dialysis Control Unit with Actril[®] Solution corresponds to the "Disinfecting the Machine" procedure on page 4-4 of the COGE Operator's Handbook. (#433126-001 Rev. A)

1. Prepare two (2) liters of disinfectant solution by diluting one (1) liter of Actril[®] Solution with one (1) liter of AAMI Quality Water.
2. Press the POWER switch OFF.
3. Turn the water supply off.
4. Disconnect the Water Supply Hose from the water source.
5. Place the end of the hose into the container of the disinfectant solution.
6. Press the POWER switch ON.
7. Press the RINSE button on. Verify that the BYPASS indicator is not lighted.
8. Hold the RINSE button down until the machine has drawn in all but a few milliliters of the disinfectant. (Pressing the RINSE button also causes the no water alarm.) It should take 15 minutes or less to draw the solution into the machine. If all of the disinfectant is not drawn into the machine in that time, verify that the RINSE button is on, then continue.
9. Press the POWER switch OFF.
10. Perform a test to verify that the machine contains the disinfectant using Renal Systems Actril[®] Indicator Test strips. Dip the Test Strip into a sample from the Drain Hose. If the strip turns dark blue or black, sufficient disinfectant is present.
11. NAME A DISINFECTANT TAG ON THE FRONT OF THE MACHINE. The tag serves as a warning that the machine contains a disinfectant solution.
12. Allow the disinfectant to dwell in the machine for 12 hours.

13. After the 12 hour dwell time is complete, rinse any disinfectant from the outside of the Water Supply Hose and connect it to a source of AAMI Quality Water for Hemodialysis. Turn the water supply on.
14. Press the POWER switch ON.
15. Press the RINSE button on. Verify that the BYPASS indicator is not lighted. Allow the machine to rinse for at least 20 minutes.
16. Take a sample from the Drain Hose and perform a residual test using Actril[®] Residual Test Strips. The test should indicate a residual level of 3 ppm or less. If the test shows an unacceptable level, verify that the RINSE button is on, then continue rinsing until an acceptable level is indicated.
17. Press the RINSE button off.
18. Remove the DISINFECTANT tag and keep it for future use.
19. Press the POWER switch OFF.
20. Turn the water supply off.

Mounting

ADMINISTRATIVE
PAGE 17 OF 43

ACCEPTED
WITH COMMENTS
MAR 09 1980



Division of Minntech Corporation
 14905 28th Avenue North
 Minneapolis, Minnesota 55441 U.S.A.
 (612) 553-3300; (800) 328-3340
 Telex: 29-0825 RSIMPLS PLOH

130815



Sterilant • Sporocidal • Virucidal • Hepatitis E • ^{HIV Virus} ~~HEP A~~ Fungicidal

Hospital ⁵ Disinfectant • Tuberculocidal

Cleaner-Sanitizer • Pre-Activated • Non-Staining • Fast-Acting



52

Actril™ is a stabilized mixture of peracetic acid, hydrogen peroxide and acetic acid formulated for use in the disinfection of artificial kidney machines. Disinfection is particularly important in advanced kidney machines used to perform hemodiafiltration with open dialyzer membranes and sodium bicarbonate-buffered dialysate solutions. Since Actril™ contains acetic acid, the build-up of "scale," precipitated calcium and magnesium carbonate, may be reduced or eliminated by regular use of Actril™.

Actril™ for machine disinfection is compatible with Renal Systems Renalin® Cold Sterilant for dialyzer reprocessing. Thus, only one chemical family is used for all your center's reuse and disinfecting needs. This prevents non-compatible chemicals from reacting with each other to damage dialysis machines and dialyzer membranes with the associated potential for patient related problems. Actril™ allows you to practice proven effective, state-of-the-art disinfection with confidence that patient and staff safety is being preserved.

Actril™ has proven to be an effective sterilant at 30 hours contact time when subjected to the sporicidal test of the American Organization of Analytical Chemists (AOAC).

As a sterilant, Actril™ completely destroys microorganisms, viruses, bacteria, spores, and fungi. It is effective against *Pseudomonas aeruginosa*, *Bacillus subtilis*, non-tuberculous *Mycobacteria (NTM)*, Hepatitis B Virus, and HIV-III/LAV. It demonstrates bactericidal, fungicidal, tuberculocidal, and virucidal properties. Actril™ is also a hospital level disinfectant at 10 minutes.

The stabilized mixture of peracetic acid, hydrogen peroxide, and acetic acid leaves no toxic residues, since after reacting with organic material, it decomposes into oxygen and acetic acid.

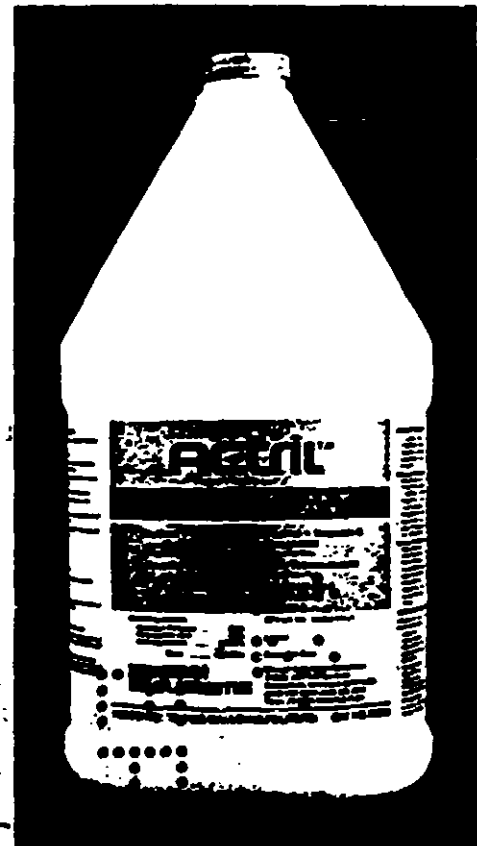
Actril™ is easy to introduce to your center, and will be readily accepted as a tool to help provide the best care possible to ESRD patients.

When used as a Sterilant.

Actril™ Cold Sterilant

- Compatible with Renalin® dialyzer reprocessing concentrate.
- No "activation" needed.
- Detailed How-To disinfect instructions.
- Conveniently packaged.
- Stable for 1 year.
- Thoroughly tested and evaluated.

From the market leader in dialysis cold sterilants, Renal Systems is pleased to introduce Actril™ Cold Sterilant. This new stable, and ready to use product is now available for the disinfection and cleaning of your hemodialysis machines. This product comes complete with detailed instructions for use.



ACTRIL™ COLD STERILANT ORDERING INFORMATION

Model	Description
78270	Actril™ Cold Sterilant (4 x 1 U.S. gallons [3.78 liters] per case)
78258	Actril™ Residual Test Strips (100 per vial)
78259	Actril™ Indicator Test Strips (500 per pack)

ACCEPTED with COMMENTS in EPA...

MAR 01 1990

522523

ADMINISTRATIVE PAGE 35 OF 285

For further details, contact your Renal Systems representative at 1-800-328-3340.



Division of Minntech Corporation
14905 28th Avenue North
Minneapolis, Minnesota 55441 U.S.A.
(612) 853-3300; (800) 328-3340
Telex: 29-0825 RSMPLS PLOH