52252-4 9/24/2013 1/12

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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

SEP 24 2013

Richard M. Ormsbee
Medivators Inc.
Technology Science Group, Inc.
14605 28th Avenue North
Minneapolis, Minnesota 55447

Subject: Minor Text Revisions on Minncare Cold Sterilant label
EPA Reg. No. 52252-4
Notification Letter Dated August 26, 2013

This letter acknowledges receipt of the Notification identified above submitted under the provisions of section 3(c)(9) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10. This Notification requests:

- Company name change
- Deleted hospital disinfection surfaces
- Deleted Dispensing Minncare with a Luer Lock Syringe use directions
- Revised container disposal statements

Based on a review of the submitted information, this notification is acceptable. This information has been made a part of your file.

Should you have any questions concerning this letter, please contact Elizabeth Watkins at (703) 347-0241.

Sincerely,

Elizabeth H. Watkins for

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

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

United States Environmental Protection Agency Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
52252-4	Marshall Swindell	[x] None [ ] Restricted
4. Company/Product (Name) Minncare Cold Sterilant	**PM#** 33	

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

Medivators Inc
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 _____
- [x] 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 deletion of use samples and alternative dispensing instructions per PR Notice 98-10.
Notification of label change per PR Notice 2007-4.
See attached 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	Manager, Reg. Affairs	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	
	Manager, Reg. Affairs	
4. Typed Name Richard M. Ormsbee	**5. Date** 8/26/2013	

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MEDIVATORS®
A Cantel Medical Company

August 26, 2013

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Regulatory Management Branch 1
Antimicrobials Division (7510C)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501
ATTN: Marshall Swindell, PM #33

RE: Notification of Minncare® Cold Sterilant (EPA Reg. No. 52252-4) Revision of Container Disposal Language in Compliance with PR Notice 9007-4 and Additional Changes per PR Notice 98-10

Dear Mr. Swindell:

The enclosed highlighted labeling has the following changes:

1. Page 1of 9: Company name change and addition of alternate text.

2. Page 5 of 9. Several examples under Hospital Disinfection have been deleted.

3. Page 7 of 9. Directions for Dispensing Minncare with a Luer Lock Syringe have been deleted.

4. The Container Disposal statement, on page 9 of 9, has been revised in compliance with PR Notice 9007-4.

Enclosed in support of the subject action, please find the following:

- Application for Pesticide (EPA Form 8570-1)
- EPA Form 8570-1 Continuation of Section 1, Explanation
- Labeling (1 copy) – Changes highlighted
- Labeling (1 copy) – Clean copy

If you have any questions I can be reached at 763-551-2689 or at rormsbee@medivators.com.

Sincerely,

Richard M. Ormsbee
Corporate Regulatory Affairs Manager
Medivators Inc

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www.medivators.com

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MINNCARE® COLD STERILANT
Master Label

For use in sanitizing of Reverse Osmosis Membranes and their associated distribution systems. Also for the sterilization and disinfection of hard surfaces and non-porous food contact surfaces.

For use in the following locations;

Industrial Laboratories
Pharmaceutical Manufacturers
Medical Products Manufacturers
Electrical Utility Companies
Dairies and Pasteurizing Facilities
Beverage and Food Processing Plants
Breweries/Wineries
Hospitals (as a disinfectant)
University Laboratories
Semi Conductor Manufacturers
Cosmetic Manufacturers
Bio Tech Companies
Animal Hospitals
Veterinary Clinics

Read the Minncare Cold Sterilant label and application notes before using this product.

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

This product must be diluted with Purified Water prior to use.

Active Ingredients	
Hydrogen Peroxide	22.0%
Peroxyacetic Acid	4.5%
Inert Ingredients	73.5%
Total	100.0%

Net Contents: _____

KEEP OUT OF REACH OF CHILDREN

DANGER - PELIGRO

See {side panel} {Directions for Use} for additional precautionary statements.

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

(Medivators logo)

Medivators Inc
14605 28th Avenue North
Minneapolis, Minnesota 55447 U.S.A.
Toll Free: (800) 444-4729
www.Medivators.com

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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.

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.	

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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

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

Physical and Chemical Hazards

This product contains an oxidizing agent.

PRODUCT EFFICACY

• Sterilant	100X dilution, 11 hours 20°C
• Sporicidal	100X dilution, 11 hours 20°C
• Bactericidal	100X dilution, 11 hours 20°C
• Virucidal	100X dilution, 11 hours 20°C
Hepatitis B	100X dilution, 11 hours 20°C
HIV-1*	100X dilution, 11 hours 20°C
• Fungicidal	100X dilution, 11 hours 20°C
• Effective against non-tuberculous mycobacterium (chelonae abscessus)	100X dilution, 10 min., 20°C
• Cleaner/Sanitizer	
(Non-food contact surfaces)	32x dilution, 10 min., 20°C
(food contact surfaces	320x dilution, 1 min., 25°C
Staphylococcus aureus and Escherichia coli)	
• Hospital Disinfectant	100X dilution, 10 min., 20°C
Pseudomonacidal	
• Broad Spectrum Disinfectant	100X dilution, 10 min., 20°C
• Germicidal Spray Disinfectant	100X dilution, 10 min., 20°C
• RO Membrane Sanitizer	100X dilution, 36 min., 20°C

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* KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/ objects likely to be soiled with blood or body fluids which can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

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 Minncare 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 Minncare Cold Sterilant.

Minncare Cold Sterilant is a single-use product not intended for reuse. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled.

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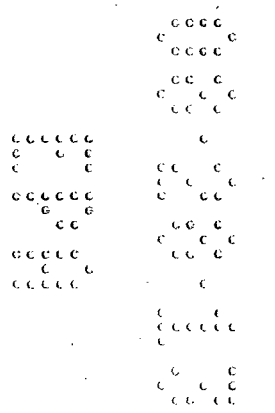
DIRECTIONS FOR STERILIZATION

Minncare 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 Minncare Cold Sterilant 100X (1 part Minncare plus 99 parts purified water). Do not store diluted Minncare Cold Sterilant for use as a sterilant; once diluted, use immediately. Immerse the item to be sterilized in a sufficient volume of diluted Minncare Cold Sterilant to cover the item and fill all passages requiring sterilization. Hold in the sterilizing solution for a minimum of 11 hours at 20°C (68°F). Remove items after 11 hours and rinse with sterile water until effluent testing shows acceptable levels when tested with Minncare Residual Test Strips.

DIRECTIONS FOR HOSPITAL DISINFECTION

Minncare Cold Sterilant is to be used on hard, non-porous surfaces such as plastic, glass, or stainless steel in settings such as hospitals, clinics, or physician's offices. Examples include counters, bed rails, bathroom fixtures and 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 Minncare Cold Sterilant 100X (1 part Minncare Cold Sterilant plus 99 parts purified water). Once diluted, the solution must be used within seven (7) days. Immerse the item to be disinfected in sufficient volume of diluted Minncare Cold Sterilant to cover the item and fill all passages requiring disinfecting. Hold in the disinfecting solution for a minimum of 10 minutes. Remove items after 10 minutes and rinse with sterile water until effluent shows acceptable levels when tested with Minncare 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.



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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 Minncare 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 Minncare 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 Minncare 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 SANITIZING OF REVERSE OSMOSIS MEMBRANES

Minncare Cold Sterilant is recommended for sanitizing reverse osmosis membranes and their associated distribution systems. This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. Minncare Cold Sterilant may not totally eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. The possibility of recontamination by the incoming water supply may exist. Minncare Cold Sterilant should be used in a sanitation program, which includes bacteriological monitoring of the entire RO water system.

Minncare Cold Sterilant may be used for reverse osmosis (RO) systems, which are compatible with diluted hydrogen peroxide solutions. The Minncare Cold Sterilant has a shelf life of one year. Minncare Cold Sterilant should not be stored at its 1% use dilution since this may compromise its effective concentration. This product is not registered for use on kidney dialyzers and dialysis machines.

The RO manufacturer should be consulted prior to use of Minncare Cold Sterilant to determine the temperature and pH range acceptable for the particular membranes. At a 100X dilution (1% concentration), the pH range for Minncare Cold Sterilant is 3.0-3.5.RO water systems vary in design according to the particular needs of the user. Because of the variations in materials of construction at different facilities, some systems may have components of pumps, gasket, etc. that are not compatible with long term exposure to Minncare Cold Sterilant. Minncare Cold Sterilant is to a degree, corrosive to copper, brass, iron and certain other metals. Minncare Cold Sterilant has also exhibited a decreased resistance to latex and Buna-N with extended exposure. Minncare Cold Sterilant Solution has been found compatible with typical system materials such

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as stainless steel. It is also compatible with polypropylene, high-density polyethylene, polysulfone, Teflon polycarbonate, neoprene, ABS, nylon, acrylic silicone, Plexiglas, ethylene propylene, VITON, FLUOREL, PVC and CPVC.

Because of the individuality of the RO water system in design and construction as well as the quality of raw feed water, all RO water does not contain the same components. Dependent upon your particular system, all or potions of the following procedure may be for sanitizing.

Biological or organic fouling of the membrane or other parts of the system should be removed with the appropriate cleaner. It is important to follow the membrane manufacturer's recommended cleaning procedure. After cleaning, flush the system. Mineral deposits should be removed with an acidic cleaner prior to sanitizing of the membrane. Again, follow the membrane manufacturer's recommended cleaning procedure. Then flush the unit with RO permeate. The presence of iron or other transition metals, in conjunction with the hydrogen peroxide in Minncare Cold Sterilant, could cause membrane degradation. Prepare a 1% solution (1 part Minncare Cold Sterilant to 99 parts water) by adding the Minncare Cold Sterilant solution to permeate water. Fill the entire water circuit to be sanitized with a 1% solution and allow the diluted solution to reach a minimum temperature of 20° (68°F). Do not exceed the membrane manufacture's recommended temperature. Recirculate the 1% Minncare Cold Sterilant solution until the entire system is filled. Allow the elements to soak in the 1% Minncare Cold Sterilant solution for a minimum of 36 minutes at 20°C (68°F).

Rinse the RO system and check for residuals by following the directions on the Minncare Residual Test Strips label. The residual test strip should indicate less than 2ppm. Rinse times will vary depending on the size of the RO system. Residual sanitizer that may enter the system because of chemical rebound can be eliminated by diverting product water to drain for a short period of time.

~~DISPENSING MINNCARE COLD STERILANT WITH LUER LOCK SYRINGE~~

~~Carefully remove the bottle of Minncare Cold Sterilant from its protective bag and open the bottle. Remove the syringe from its protective bag. Depress syringe plunger fully into syringe. Insert syringe into bottle until below the surface of the liquid. Slowly pull the syringe plunger back to draw Minncare Cold Sterilant into the syringe until 10cc are in the syringe. Replace the cap on the bottle and re-seal the bottle in its protective bag. Attach the Luer lock end of the syringe to the male Luer lock port of a Minntech Fiberflo capsule filter or the comparable fitting on any device being disinfected. Inject the appropriate amount of Minncare Cold Sterilant into the device to achieve a 1% concentration of Minncare.* Dispose of any excess Minncare Cold Sterilant as directed by the Disposal Instructions and discard the syringe.* Test appropriate Minncare Cold Sterilant concentration using the 1% test strips. Let the Minncare Cold Sterilant solution soak the device for a minimum of 36 minutes. Rinse the device with purified water and check for residuals by following the directions on the Minncare Residual Test Strip label. The residual level should indicate less than 2 ppm.~~

~~* Read Minncare Cold Sterilant Direction for Use very carefully so you fully understand the precaution and protection you must take when using Minncare Cold Sterilant.~~

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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 a 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 of soiled. Apply solution to surface or immerse items to be sanitized in the solution. Minncare Cold Sterilant may be applied by cloth, mop or sponge. Allow 10 minutes of contact time. Rinse with purified water, drain excess, if possible, and allow to air dry.

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

Minncare Cold Sterilant may be used to sanitize hard, non-porous surfaces such as glass or stainless steel used in fillers, pipelines, silos, processing vats, bulk tanks and utensils used in dairies, food processing plants, wineries and breweries. 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 Minncare Cold Sterilant at 2 ounces to 5 gallons of water. Use fresh solution with each use. Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled. 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:

- Reverse Osmosis Membranes and Associated Distribution Systems
- Plastic Items
- Stainless Steel Objects or containers e.g. bedpans, tanks
- Hard Surfaces e.g. counters, sinks, bulk tanks etc.
- Floors, Walls, Bathroom Fixtures, Vinyl surfaces
- Formica surfaces
- Glass

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STORAGE AND DISPOSAL

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

Pesticide Storage

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

Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available.

(For ≤ 5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after flow begins to drip. Repeat this procedure two more times.

(For >5 gal.): Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten enclosures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand container on its end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.