

actril®

Actril® Cold Sterilant



RESEARCH REPORT

Fast, Safe, Reliable Surface Disinfection for the Life Sciences Market

TECHNICAL NOTES and RESEARCH DATA REPORT

Actril Cold Sterilant

Fast, Safe, Reliable Surface Disinfection for the Life Sciences Market

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Overview - Mar Cor Purification

Who is Mar Cor Purification?

Mar Cor Purification is the marketer of Medivators's peracetic acid-based disinfectant products to industrial and non-dialysis medical markets. Mar Cor Purification distributes Minncare® Cold Sterilant and Actril® Cold Sterilant through industrial distribution, OEM's and directly to end users. Mar Cor Purification has offices in 27 cities in the U.S. and Canada plus sales and distribution offices in the Netherlands and Singapore. Mar Cor Purification's manufacturing facilities are located in Minneapolis, MN and Burlington, Ontario.

Both Mar Cor Purification and Medivators are part of Cantel Medical Corp. Cantel Medical Corp. is a leading provider of infection prevention and control products in the health care market. Their products include specialized medical device reprocessing systems for renal dialysis and endoscopy, dialysate concentrates and other dialysis supplies, disposable infection control products primarily for the dental industry, endoscopy and surgical products, water purification equipment, sterilants, disinfectants and cleaners, hollow fiber membrane filtration and separation products for medical and non-medical applications, and specialty packaging for infectious and biological specimens. Cantel Medical Corp., through its subsidiaries, also sells scientific instrumentation products, provides technical maintenance for its products and offers compliance training services for the transport of infectious and biological specimens.

Mar Cor Purification and Sterilants

Environmentally safe sterilants and disinfectants.

ACTRIL and MINNCARE are two of the oldest and most trusted sterilants. Actril Cold Sterilant, introduced in 1987, replaced formaldehyde and glutaraldehyde with a stabilized mixture of peracetic acid, hydrogen peroxide and acetic acid for powerful disinfection of medical devices without harmful aldehyde by-products. Beyond medical device reprocessing, these sterilant technologies have found numerous applications in other clinical and industrial settings.

Bacteria control is an important concern in laboratories and manufacturing environments that maintain high-purity water systems. Minncare Cold Sterilant has been cleaning and sanitizing reverse osmosis membranes and water distribution systems since 1989. Backed by years of extensive research and proven performance, peracetic acid-based sterilants and disinfectants are completely formaldehyde-free and glutaraldehyde-free to safeguard users, health care personnel and the environment.

Actril Cold Sterilant

What is Actril Cold Sterilant?

Actril Cold Sterilant is a stabilized mixture of peracetic acid, hydrogen peroxide and acetic acid. Because it is formaldehyde-free and glutaraldehyde-free, Actril Cold Sterilant allows you to practice proven, effective, state-of-the-art disinfection while safeguarding your workers.

Peracetic Acid as a Sterilant

Beyond medical device reprocessing, peracetic acid has been accepted worldwide in the pharmaceutical, food processing and beverage industries. Its powerful antimicrobial action at low temperatures and absence of toxic by-products make peracetic acid appropriate for applications in pharmaceutical, biotech, meat and poultry processing plants, canneries, dairies, breweries, wineries, soft drink plants and agriculture. Peracetic acid is also ideal for clean-in-place (CIP) systems, and is used as a terminal disinfectant or sterilant for stainless steel and glass tanks, piping, tank trucks and railroad tankers.¹

Worldwide acceptance.

Peracetic Acid Method of Action

Peracetic acid reacts with sulfhydryl and sulfur-sulfur bonds in proteins as well as carbon-carbon double bonds as found in many lipids.² As a result, the peracetic acid can deactivate critical enzymes and disrupt cell membranes by oxidizing membrane components.

Registration of Actril Cold Sterilant

Actril Cold Sterilant can be sold in the United States (EPA Reg. No. 52252-7), the European Union, as well as several Central and South American countries. Actril Cold Sterilant carries the CE mark.

Certifications.

Fast Acting Actril Cold Sterilant

Actril Cold Sterilant is fast, effective and does not require heating.

| Efficacy Claim | Exposure Time | % Kill |
|--|---------------|--------|
| Sterilization* @ 20°C (68°F) | 5.5 hours | 100% |
| High Level Disinfection* (Tuberculocidal) @ 20°C (68°F) | 10 minutes | 100% |

How quick is Actril Cold Sterilant?

*Sterilization is defined as the destruction of all living organisms and is verified by the germicide's ability to destroy bacterial endospores. The exposure time for high-level disinfection is established by determining the time required for the germicide to destroy high numbers of mycobacteria.

Actril Cold Sterilant is Ready to Use

Actril Cold Sterilant is convenient, ready to use and requires no mixing, activation or dilution.

Convenient Ready-to-use formula

Efficacy of Actril Cold Sterilant

Testing demonstrates that as a full strength sterilant, Actril Cold Sterilant completely destroys all microorganisms, including: viruses, bacteria, spores and fungi. It is effective against *Pseudomonas aeruginosa*, *Bacillus subtilis*, nontuberculosis mycobacteria (NTM), hepatitis B virus and HIV (the virus associated with AIDS). When subjected to the testing accepted by the American Organization of Analytical Chemists (AOAC), the EPA, and the FDA, Actril Cold Sterilant has proven to be an effective sterilant.

Efficacy of Actril Cold Sterilant?

| Type | Organism | Contact Time Tested at 68°F (20°C) | Test Results |
|-----------------------|---|--|---|
| Spores | <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i> | 5.5 hours | 100% kill of ≥ 104 endospores |
| Mycobacteria | <i>Mycobacterium bovis</i> | 10 minutes | 100% kill of ≥ 106 microorganisms |
| Vegetative Organisms | <i>Pseudomonas aeruginosa</i> <i>Salmonella choleraesuis</i> <i>Staphylococcus aureus</i> | 10 minutes Diluted 1:10 | 100% kill of ≥ 104 bacteria |
| Fungi | <i>Trichophyton mentagrophytes</i> | 10 minutes | 100% kill of ≥ 105 spores |
| Non-lipid small virus | Polio virus Type 2 | 15 minutes | 100% kill of ≥ 105 viruses |
| Lipid medium virus | Herpes simplex Type 1,2,HIV (AIDS virus) | 3 minutes Herpes - Diluted 1:10 HIV - Diluted to MEC | 100% kill of Herpes ≥ 103.2 viruses 100% kill of HIV ≥ 104 viruses |
| Hepatitis B and C | No approved method to test for hepatitis B&C exists.* | N/A | N/A |

* A direct test is unavailable, however they are generally considered easier to kill than Polio viruses.

Actril Cold Sterilant and Surface Challenge Test (USP <1072>)

This testing focused on testing two surfaces, Stainless Steel 316 and Polycarbonate (Lexan) against five microorganisms commonly found in cleanrooms: *Pseudomonas aeruginosa*, *Aspergillus niger*, *Mycobacterium terrae*, *Bacillus subtilis* and Polio virus Type 1 Strain Chat.

This testing was done according to the USP <1072> Guideline for the Surface Challenge Test. All of these organisms are listed in this document as Clinically Important.

| Test Results - Table 1: Average Log Reduction | | | | | | |
|---|--------|-------------------------------|--------------------------|-----------------------------|--------------------------|--------------|
| | | <i>Pseudomonas aeruginosa</i> | <i>Aspergillus niger</i> | <i>Mycobacterium terrae</i> | <i>Bacillus subtilis</i> | Polio virus* |
| Lexan Carrier | 3 min | 5.0 | 4.2 | 4.4 | 0 | 2.6 |
| | 5 min | 5.0 | 4.6 | 4.0 | 3.5 | 3.8 |
| | 10 min | 5.0 | 4.7 | 4.4 | 3.5 | 4.5 |
| Stainless Steel Carrier | 3 min | 4.2 | 2.85 | 4.4 | 0 | 3.9 |
| | 5 min | 4.2 | 4.8 | 5.0 | 3.6 | 3.9 |
| | 10 min | 4.2 | 4.7 | 5.0 | 3.6 | 4.1 |

*For possible cytotoxicity of materials, see final report A07017: To reduce cytotoxicity, the culture went through a Sephadex Gel Filtration. ATS still experienced a cytotoxic effect with stainless steel and lexan; since this phenomenon will be seen in cleanroom facilities, it was included in the log reduction numbers. The log reductions taken from ATS Lab report report A07017 come from initial population counts.

The Useful Life of Actril Cold Sterilant

Actril has a shelf life of one year. The expiration date of Actril Cold Sterilant is printed on the front panel of the bottle label. Even upon opening the bottle, Actril Cold Sterilant will maintain its germicidal activity if not used and if re-sealed. This is because it does not require an activator like glutaraldehyde, which decays after activation and must be discarded.

How long does Actril Cold Sterilant last?

Actril Cold Sterilant Material Compatibility

Actril Cold Sterilant has been tested and shown to be compatible with material coupons and medical devices made from the materials shown below:

Actril is compatible with most common surfaces.

| Metals | Plastics | Elastomers |
|-----------------------|--------------------------------------|-----------------|
| Stainless Steel (316) | Polypropylene | Silicone rubber |
| Aluminum Alloy (6061) | Perfluoroalkoxy (PFA) | |
| | Acrylonitrile-butadienestyrene (ABS) | |
| | Polyethylene | |
| | Polyvinylchloride (PVC) | |
| | Polycarbonate | |
| | Tygon | |

Do not use Actril Cold Sterilant with brass or copper.

Other materials not listed should be tested for compatibility prior to use.

Biodegradability of Actril Cold Sterilant

The stabilized mixture of peracetic acid, hydrogen peroxide and acetic acid leaves no toxic residues. After reacting with organic material, Actril Cold Sterilant decomposes into oxygen and acetic acid. In addition, it is biodegradable in waste water.

Is Actril Cold Sterilant biodegradable?

Actril Cold Sterilant Safety

Actril Cold Sterilant has been extensively tested both for potential toxicological effects to the user (environmental toxicity) and to the patient (patient toxicity). Completely aldehyde free, Actril Cold Sterilant enhances worker safety and protects the environment.

Actril is safe to use.

Actril Cold Sterilant Environmental Toxicity Testing

| TEST | RESULTS |
|----------------------------|----------------------------|
| Acute inhalation toxicity | No toxic symptoms observed |
| Primary dermal irritation | Non-irritant to skin |
| Subchronic dermal toxicity | Not dermally toxic |
| Dermal sensitization test | Not a dermal sensitizer |
| Skin corrosion test | Not corrosive to skin |
| Primary eye irritation | Corrosive to ocular tissue |
| Acute oral toxicity | LD ₅₀ = 50 g/kg |

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Actril Cold Sterilant Patient Toxicity Testing

| TEST | RESULTS |
|---------------------------------|---|
| Cytotoxicity MEM agrose overlay | Non-cytotoxic at 1:1000 dilution |
| Hemolysis "in vitro" test | Non-hemolytic at 500 ppm peracetic acid |

Handling Requirements for Actril Cold Sterilant

Users are likely to detect the odor of vinegar when using Actril Cold Sterilant. The main active ingredient in Actril Cold Sterilant is peracetic acid, which forms through a chemical reaction between acetic acid and hydrogen peroxide. Excess acetic acid is present in Actril Cold Sterilant to ensure that adequate amounts of peracetic acid are produced. Acetic acid is the main component in vinegar.

In a safe working environment under normal use conditions, special ventilation is not required. Independent testing indicates that under normal use conditions, levels for hydrogen peroxide and acetic acid, two of the main Actril components, are well below established permissible exposure limits (PEL). There is no Occupational Safety and Health Administration (OSHA) PEL for peracetic acid, the main active ingredient in Actril Cold Sterilant. When working with any liquid chemical germicide, a safe working environment that minimizes spills and undue exposure is always recommended as standard practice.

Although environmental toxicity testing indicates that Actril Cold Sterilant is a user-friendly product, it is still a liquid chemical and should be handled as stated in the Actril Directions for Use. Eye protection should always be worn since Actril Cold Sterilant is corrosive and can cause eye damage. In case of contact with eyes, flush with large amounts of water for at least fifteen (15) minutes and get prompt medical attention.

Even though Actril Cold Sterilant is not a skin irritant, skin sensitizer, nor a skin corrosive; rubber gloves should be worn at all times. For a chemical emergency, spill, leak, fire, exposure or accident; call Chemtrec, Inc., day or night, at 1-800-424-9300. Outside the continental U.S., call 1-703-527-3887.

What are Actril Cold Sterilant's handling requirements?

Spill Clean Up with Actril Cold Sterilant

Since Actril Cold Sterilant decomposes naturally, accidental spills can be cleaned up and discarded directly down the sewer drain. No neutralization of Actril Cold Sterilant is normally required but users should confirm this with their local authorities. Always follow the handling instructions as specified in the “Actril Directions for Use”.

Disposal of Actril Cold Sterilant

Actril Cold Sterilant liquid can be disposed of directly into the sewer drain. In fact, peracetic acid has been investigated as a disinfectant for sewage and sewage effluents. Peracetic acid's unique broad spectrum activity in the presence of organic matter and decomposition into natural components makes it a potentially ideal sewage treatment processing product. Actril Cold Sterilant decomposes naturally into oxygen, water and acetic acid.

How do I dispose of Actril Cold Sterilant?

Even though Actril Cold Sterilant is not a skin irritant, skin sensitizer, nor a skin corrosive, rubber gloves should be worn at all times. For a chemical emergency, spill, leak, fire, exposure, or accident, call Chemtrec, Inc., day or night, at 1-800-424-9300. Outside the continental U.S., call 1-703-527-3887.

References

1. Block, S.S., Ph.D., Disinfection, Sterilization, and Preservation. 4th ed. Philadelphia: Lea & Febiger; 1991, p. 177.
2. Block, S.S., Ph.D., Disinfection, Sterilization, and Preservation. 4th ed. Philadelphia: Lea & Febiger; 1991, p. 172.
3. [US EPA] United States Environmental Protection Agency, Office of Pesticides and Toxic Substances. 1984. Re-use test protocol specifications.

Additional Documentation

1. Residuals of Peroxide on Surfaces after Minncare and Actril Evaporate. Mar Cor Purification Technical Bulletin: 2008.
2. Actril Master Label.
3. Clostridium difficile Endospores and PAA Germicides. Mar Cor Purification Technical Bulletin: 2008.
4. Virucidal Efficacy of a Disinfectant for Use on Inanimate Surfaces (Polio virus Type 2). Test Report: 1995.
5. Actril and Minncare Cold Sterilants: Effectiveness against MRSA & MSSA. Mar Cor Purification Technical Bulletin: 2007.
6. William Rutala, PhD, David Weber, MPH, et. al. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. CDC Website. November 2008.
7. Actril Tech Notes and Data Research Report. Medivators Corporation: 1999.
8. Residuals of Peroxide on Surfaces after Minncare and Actril Evaporate. Mar Cor Purification Technical Bulletin: 2008.

Cold Sterilants and Support Products

ACTRIL - Ready to Use and Fast Acting

Actril Cold Sterilant.

Actril Cold Sterilant is another powerful peracetic acid and hydrogen peroxide disinfectant in ready-to-use form. It is a fast-acting disinfectant that is effective against a broad spectrum of organisms, including bacteria, mycobacteria, yeast, molds, fungal spores, bacterial spores and viruses. The only alternative to aldehyde for sporicidal activity.

MINNCARE - Concentrated Multipurpose Disinfectant

MinnCare Cold Sterilant.

MinnCare Cold Sterilant is a powerful disinfectant containing a concentrated mixture of peracetic acid and hydrogen peroxide. For over 20 years, MinnCare has been the leading disinfectant that is proven effective against a broad spectrum of organisms, including bacteria, mycobacteria, yeast, molds, fungal spores, bacterial spores and viruses. Unlike many disinfectants used in the clean room industry, MinnCare Cold sterilant is not only germicidal but also sporicidal and tuberculocidal - allowing your facility to limit the number of disinfectants used.

Assured Success with Test Strips

Test Strips.

Mar Cor Purification is the only supplier to provide Test Strips validated for use with these disinfectants. MinnCare and Actril Test Strips give quick results with easy-to-read indicators. Use the convenient dip-and-read MinnCare 1% Test Strips or Actril 1% Test Strips as a pass/fail measurement for adequate concentration of sterilant. Use the MinnCare Residual Test Strips or Actril Residual Test Strips to test for complete rinse-out of disinfectant from a piping system.

| Part Number | Description | Quantity |
|----------------------|--|-------------------------------|
| In The United States | | |
| 176-02-046 | Actril Surface Disinfectant | 6x1 liter case |
| 176-02-043 | Actril Surface Disinfectant | 4 x 1 gallon |
| 176-02-044 | Actril Surface Disinfectant with Test Strips | 4 x 1 gallon w/ test strips |
| 176-02-045 | Actril Surface Disinfectant Drum | 50 gallon drum |
| 3024761 | Chemflex Refillable Dry Wipe System | Includes six wipe rolls |
| 3024980 | Actril (Clean Room Packaging) US | 6 x 1 liter case w/6 sprayers |
| 176-02-051 | Spray head for Actril liters | 1 Spray head |
| 185-40-008 | Actril Residual Strips | 100 per vial |
| 185-40-009 | Actril Indicator Strips | 500 per vial |
| In Canada | | |
| 78400-258 | Actril Surface Disinfectant (DIN: 02001020) | 6 x 1 liter case |
| 78400-446 | Actril Surface Disinfectant | 2 x 5 liter case |
| 78400-287 | Chemflex Refillable Dry Wipe System | Includes six wipe rolls |
| 78400-340 | Actril (Clean Room Packaging) | 6 x 1 liter case w/6 sprayers |
| In Europe | | |
| 176-02-053 | Actil Cold Sterilant | 2 x 5 liter case |
| 176-02-056 | Actil Cold Sterilant | 6 x 1 liter case |
| 3024982 | Actril (Clean Room Packaging) Europe | 6 x 1 liter case w/6 sprayers |
| In Asia | | |
| 78397-640 | Actil Cold Sterilant | 2 x 5 liter case |
| 78399-482 | Actil Cold Sterilant | 6 x 1 liter case |
| 78400-226 | Actril (Clean Room Packaging) Asia | 6 x 1 liter case w/6 sprayers |

MinnCare Cold Sterilant is registered with the US Environmental Protection Agency (EPA Registration Number 52252-4). Actril Cold Sterilant is registered with the US Environmental Protection Agency (EPA Registration Number 52252-7).

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