

Actril® Cold Sterilant

Research Report: Surface Challenge Test (USP <1072>)

Fischer-Robertson, Inc.
3890 Symmes Road
Hamilton, OH 45015
ph 513-860-3445 fx 513-860-4744
www.fischer-robertson.com

Introduction

Actril Cold Sterilant is an US EPA registered disinfectant that has a broad range of disinfection claims. Actril Cold Sterilant is used in a wide range of healthcare and clean room facilities. This technical white paper examines the use of Actril Cold Sterilant in a pharmaceutical manufacturing environment that complies with USP-NF <1072>: Disinfectants and Antiseptics.

Actril Cold Sterilant

Actril Cold Sterilant is a ready to use peracetic acid and hydrogen peroxide based liquid disinfectant that has been extensively used in hospitals, clinics and cleanrooms for over 20 years. Besides being extremely efficacious against a wide range of microorganisms (including spores), Actril Cold Sterilant leaves virtually no residuals¹ and breaks down into water, acetic acid and oxygen. For more information on residuals, see "Residuals".

Selection of a Disinfectant for Use in a Pharma Manufacturing Environment

USP <1072> outlines both the factors affecting and the process of selecting an appropriate disinfectant for the pharmaceutical manufacturing environment. Key factors mentioned in the document are: (1) spectrum of activity of the disinfectant, (2) EPA claims, (3) concentration of the disinfectant, (4) surface material to be disinfected, (5) organic matter and load on the surfaces, (6) need for residual bactericidal activity, (7) corrosivity with multiple applications, (8) operator safety, (9) compatibility of the disinfectant with other cleaners or disinfectants, (10) disinfectant rotational plan, and (11) steps that need to be taken to ensure the disinfectant does not contaminate the pharmaceutical. Each of these factors needs to be thought through in the evaluation of a disinfectant.

In terms of process, USP <1072> outlines three tests on effectiveness that may be necessary to conduct. The first test is a USE DILUTION test against the targeted organisms. This test involves the placing of a contaminated article (of known

quantity and type) into the test disinfectant. At the end of a determined time period, the contaminated article is removed, neutralized, and tested for log reduction. For US-EPA products, the testing submitted for label claims is the same test methodology described here.

The second test outlined is the Surface Challenge Test. The Surface Challenge Test unlike the Use Dilution test does not immerse the test articles in the target disinfectant. Instead test surface coupons (of the same surface material used in the cleanroom) are inoculated with the target organism and incubated. Once the organisms are grown to sufficient levels, testing is initiated, where the disinfectant is applied to the test coupons for the predetermined contact time. At the end of this time, the coupons are neutralized and tested for log reduction. In this testing, the recommended log reduction for bacteria and viruses is 10³ and for spores is 10².

The third test, unlike the first two tests, looks at the actual outcomes of the disinfection. Basically, it looks at the microbial changes pre and post disinfection to determine the successfulness of the disinfection.

Use Dilution Test

Extensive use dilution tests have been performed with Actril Cold Sterilant against a wide range of organisms including: (1) Spores: *Bacillus subtilis*², *Clostridium sporogenes*², *Clostridium difficile*³, (2) Myobacteria: *Mycobacterium bovis*², (3) Viruses: Polio Virus Type 2⁴, Herpes Simplex Type 1 and 2, HIV, (4) Fungi: *Trichophyton metagrophytes*², and (5) Vegetative Bacteria: *Pseudomonas aeruginosa*², *Salmonella choleraesuis*², *Staphylococcus aureus*², and MRSA⁵. These tests were conducted according to AOAC protocols (or modified AOAC protocols).

Surface Challenge Tests

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 organisms.

Test Procedure

Ten 2" x 2" coupons for each material were inoculated with the desired organism and dried for 30 minutes (except for the Polio virus, which three 2" x 2" coupons of each material were used). A spray bottle containing Actril was used to fully wet the coupon with the germicide. Coupons were neutralized after 3, 5, and 10 minutes; counts were enumerated from the surviving organisms. Controls were carried out to validate the test method's legitimacy.

Discussion

The choosing of the right disinfectant is critical for a pharmaceutical cleanroom not only because potential losses due to contaminated product but also because of user safety, as well as, room turnaround. Current disinfectants such as 70% IPA, while having

fairly quick kill against some organisms are not able to kill the most tenacious organisms such as spores like Bacillus subtilis, as well as, some viruses.⁶

In our testing (see table 1), however, we have seen that in the Surface Challenge Tests against a wide range of organisms Actril Cold Sterilant is very effective in achieving the target log reductions (3 log for bacteria and viruses and 2 log for spores) in 3 to 5 minutes, depending on the organism. Most significantly, Actril Cold Sterilant was able to achieve a 3 plus log reduction on spores (Bacillus subtilis) in just 5 minutes.

Actril Cold Sterilant has been used for cleanroom work area disinfection for over 10 years. Besides the tests included in this report, Minntech Corporation has conducted a number of other tests relevant to cleanroom disinfection: AOAC Use Dilution Tests⁷, Residuals⁸, and Material Compatibility⁷.

Table 1. Test Results - Average Log Reduction

		Pseudomonas aeruginosa	Aspergillus niger	Mycobacterium terrae	Bacillus subtilis	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.

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. Minntech Corporation: 1999.

⁸ Residuals of Peroxide on Surfaces after Minncare and Actril Evaporate. Mar Cor Purification Technical Bulletin: 2008.

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