Summary of Microbiological Studies Performed on SALSHA® SALSHA-Cide™ 28 HLD

Reusable Sterilizing & High Level Disinfecting Solution

June 2013

DESCRIPTION:

Sporicidal and tuberculocidal tests were conducted side-by-side against predicate device Cidex Plus in order to validate sterilization and high level disinfection claims. The lab efficacy tests were conducted on 28 day stressed product at or below the minimum effective concentration of 1.8% glutaraldehyde.

STERILIZATION CLAIM:

The contact time of 10 hours at 25°C is supported by AOAC Sporicidal Test data. Three lots of stressed products were tested against spores dried on carrier surfaces. The test results showed that all spores were eliminated and no positive cultures were observed. Confirmatory AOAC Sporicidal tests were performed on two lots of disinfectant with satisfactory results.

"AOAC Sporicidal Test"

Tested against micro-organisms: C. Sporegenes, B. Subtilis

"Sporicidal Activity of Disinfectants: AOAC Official Methods of Analysis Test 966.04"

Tested against micro-organisms: C. Sporegenes, B. Subtilis

"AOAC Sporicidal Range Confirmation Test End Point Analysis"

An end point of the total kill contact time for spores was carried out to demonstrate that an adequate safety margin has been incorporated into the contact time of 10 hours at 25°C. Tested against micro-organisms: Bacillus Subtilis

HIGH LEVEL DISINFECTION CLAIM:

The contact time of 10 hours at 25°C is supported by Quantitative Tuberculocidal test data. Other efficacy tests performed for vegetative bacteria, fungi and viruses showed satisfactory results at less than 5 minutes at 20°C. Additional tests were performed to demonstrate effectiveness in simulated and actual use conditions for endoscopes at 25°C for 25 minutes.

"Quantitative Tuberculocidal Test SALSHA-Cide 28 HLD Glutaraldehyde and Predicate"

Tested against micro-organisms: Mycobacterium bovis

"AOAC Use Dilution Test"

Tested against micro-organisms: Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa

"AOAC Fungicial Effectiveness Test"

Tested against fungus: Trichophyton mentagrophytes

EFFICACY REPORT

"Virucidal Effectiveness Test"

Tested against viruses: Herpes simplex I, Poliovirus, Type II

"Virucidal Efficacy of Disinfectants for Use on Inanimate Environmental Surfaces"

Tested against virus: Human Immunodeficiency Virus (HIV)

"Tuberculocidal Test using Medical Devices Simulated Use Test after Twenty Eight Days Use-Re-Use Stress"

A simulated use test was conducted in the laboratory to support the contact condition for high-level disinfection of endoscopes at 25°C for 25 minutes. The test demonstrates the effectiveness to kill M. Terrae dried on flexible fiber endoscopes. Tested against micro-organism: Mycobacterium terrae.

"Reprocessing Flexible Fiber Endoscopes in Use Studies"

Reprocessing flexible fiber endoscopes in-use studies demonstrate the effectiveness of the disinfectant in actual use conditions. The manual reprocessing followed the ASTM 1518-94 protocol. Tested against various human flora micro-organisms from clinical patients. Staphyloccus aureus was used as the neutralizer effectiveness control.

STRESSED TEST

Three lots of product were stressed in order to carry out certain tests under worst case conditions. Simulated reprocessing was carried out according to an EPA "Reuse Test Protocol Specifications." Use-Re-Use Manual Stressing stressed the test agents and predicate product for 28 days, consistent with the maximum reuse life of the product. Chemical determinations were made of the percent glutaraldehyde to verify that the stressed material was at or below the Minimum Effective Concentration.

"Use-Re-Use Manual Stressing Liquid Chemical Germicide Test"

D-VALUES

D-Value Comparisons, Range Finding Studies at both 20°C and 25°C were conducted to evaluate relative sporicidal activity against Bacillus spores. The D-values were calculated and plotted graphically.

"Range Finding Studies D-Value Comparisons"

Tested against micro-organism: Bacillus subtilis