



SporGon

High-Level Disinfectant/ Sterilizing Solution Technical Data Sheet

- BRIEF DESCRIPTION -

SporGon is a ready-to-use hydrogen peroxide/peracetic acid-based high-level disinfectant and sterilant. Its ready-to-use formula requires no mixing and no activation. It has broad spectrum efficacy against bacteria, virus & fungi including TB, and many other pathogenic organisms. SporGon also passed the AOAC Sporicidal Test effectiveness in killing the spores of Bacillus subtilis and Clostridium sporogenes in three hours and thus met the FDA established criteria for chemical sterilant (FDA 510K Clearance). SporGon achieves high-level disinfection in 15 minutes and sterilization in 3 hours at room temperature.

SporGon is far less toxic than gluteraldehyde-based high-level disinfectants and is far less corrosive than chlorinated disinfectants. No test strip is required to test the concentration of active ingredients and solution can be reused for medical devices for 14 days when used as directed.

- USE PROTOCOL -

Directions for High-level Disinfection:

SporGon achieves high-level disinfection (destroys all pathogenic microorganisms, except for large numbers of bacterial endospores, but including *Mycobacterium* strains as represented by *M. bovis*-Quantitative TB method) when used according to the Directions for Use at 68°F (20° C) with a contact time of 15 minutes . (For a medical device reuse period not to exceed 14 days.)

Directions for Sterilization:

SporGon achieves sterilization (eliminates all microorganisms including *Clostridium sporogenes* and *Bacillus subtilis* spores) when used or reused according to the Directions for Use at 68° (20° C) with a contact time of 180 minutes (3 hours). (For a medical device reuse period not to exceed 14 days.)

Directions for Use: Refer to package insert (reprinted at the end of this bulletin) for more detailed product usage/data.

-ACTIVE INGREDIENTS-

Hydrogen peroxide7.35 %
Peracetic Acid0.23%

-EFFICACY-

Organism With Spores Contact Time

Bacillus subtilis 180 minutes
Clostridium sporogenes 180 minutes

Vegetative Organisms

Mycobacterium bovis 15 minutes
Staphylococcus aureus 3 minutes
Salmonella choleraesuis 3 minutes
Pseudomonas aeruginosa 3 minutes

Fungi

Trichophyton mentagrophytes 5 minutes

Viruses

Non-lipid Small Virus
Polio 2 5 minutes
Lipid Medium Virus
Herpes simplex 5 minutes
HIV-1 5 minutes

SporGon[®] High-Level Disinfectant/Sterilizing Solution Technical Data Sheet

-Medical Device Sterilization- -Reuse Period-

SporGon has demonstrated efficacy in the presence of 5% organic soil contamination and a simulated amount of microbiological burden during reuse. The hydrogen peroxide and peracetic acid concentration of this product will remain stable and effective during its use life (14 days reuse for medical devices). **SporGon must be discarded after 14 days.** Due to the lack of test strips for monitoring the concentration of active ingredients, the reuse period is limited to 14 days.

- STORAGE AND DISPOSAL -

STORAGE. The shelf life for SporGon is two years from date of manufacture. Store in its original sealed container at room temperature 15°- 30°C (59°- 86°F). **DO NOT ALLOW SPORGON TO FREEZE.**

CONTAINER DISPOSAL. Container must be triple rinsed and disposed of in accordance with federal, state and/or local regulations.

USED SOLUTION DISPOSAL. Used solution should be disposed of in accordance with federal, state and/or local regulations.

DISPOSAL OF INFECTIOUS MATERIALS. Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

- PRECAUTIONARY STATEMENTS -

KEEP OUT OF REACH OF CHILDREN.

Contains Hydrogen Peroxide and Peracetic Acid. Direct contact is corrosive to exposed tissue, causing irreversible eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. Appropriate hand, eye, and face protection (goggles, face shield or safety glasses) as well as liquid proof gowns should be

worn when cleaning and sterilizing/ disinfecting soiled devices and equipment. Avoid contamination of food. Use in a well-ventilated area in closed containers. Wash thoroughly with soap and water after handling. Harmful if inhaled. Avoid breathing (vapor or spray mist). Remove contaminated clothing and wash before reuse.

Statement of Practical Treatment In case of contact, immediately flush eyes or skin with copious amounts of water for at least 15 minutes. For eyes, get medical attention. Harmful if swallowed. Drink large quantities of water and call a physician immediately.

NOTE TO PHYSICIAN. Probable mucosal damage may contraindicate the use of gastric lavage.

-PACKAGING -

1 Gallon (3.8 L) / 4 per case

- AVAILABILITY -

<u>Manufactured for:</u>	<u>Item</u>	<u>Cat. No.</u>
Decon Labs, Inc.	1 Gallon.	4301

For Additional Technical Information call
Decon Customer Service
(800) 332-6647 or
See our Website at www.deconlabs.com

®Decon Labs, Inc.

Revised 11/2006