



ClearKlens

Bi-Spore SC

VH26

Sterile Sporicidal System

Description

ClearKlens Bi-Spore SC is an aseptically filled two part system for the creation of chlorine dioxide presented as an Activator and Base solution. ClearKlens Bi-Spore SC is a sterile disinfectant designed for hard surfaces and equipment externals in critical Pharmaceutical cleanroom areas. The sterile contents, and double bag packaging, ensure that potential contamination is not transferred into the manufacturing area.

Key properties

- ClearKlens Bi-Spore SC is a chlorine dioxide generating system.
- ClearKlens Bi-Spore SC is aseptically filled in a class 10,000 (ISO Class 7) environment, where the product is exposed during filling a class 100 (ISO Class 5) is employed.
- ClearKlens Bi-Spore SC is 0.2 µm filtered.
- ClearKlens Bi-Spore SC is double bagged to eliminate environmental contamination of the cleanroom.
- ClearKlens Bi-Spore SC is packaged in 2 x 100 ml single shot bottles for ease of dilution into 4.8 litres of water.
- ClearKlens Bi-Spore SC possesses a virucidal activity on Polio and Parvovirus in 1 minute.
- ClearKlens Bi-Spore SC possesses a fungicidal activity on A.niger in 15 minutes.
- ClearKlens Bi-Spore SC possesses a sporicidal activity within 5 minutes contact time (0% BSA).

Benefits

- Excellent sporicidal activity (passes EN 13704)
- Excellent virucidal activity (passes EN 14476)
- Broad spectrum activity even at very short contact time
- 0.2 µm filtered and aseptically filled to ensure sterility
- Each batch is sterility tested
- Each 100 ml unit is double bagged for easy transfer into the cleanroom
- Low corrosion profile
- Boric acid free

Use instructions

ClearKlens Bi-Spore SC is designed for wiping and mopping applications. Add the 100 ml contents of ClearKlens Bi-Spore SC Base to 4.8 litres of purified or WFI quality water, then immediately add the 100 ml contents of ClearKlens Bi-Spore SC Activator. Leave for 2 minutes prior to use. Use solution within 24 hours





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Technical data

Appearance: Clear pale yellow liquid

pH value (neat): 2.5 to 5

Density (20°C): 1.000 to 1.010

Available CO₂ content: 40-60 ppm

The above data is typical of normal production and should not be taken as a specification.

Safe handling and storage information

Store in original closed containers away from sunlight and extremes of temperature. Full guidance on the handling and disposal of this product is provided in a separate Safety Data Sheet. Monitoring to establish chlorine dioxide levels in the air must be performed at the site of application while ClearKlens Bi-Spore SC is in use. In the absence of monitoring data, use of a chemical respirator during product application is required. For professional use only.

Product compatibility

ClearKlens Bi-Spore SC, when applied at the recommended concentration and temperature is suitable for use on the grades of stainless steel commonly found in the Pharmaceutical industry. In the event of uncertainty it is advisable to evaluate individual materials before any prolonged use.

Test method

Validated titration test method available on request.

Each lot is provided with a Certificate of analysis, available on www.clearklens.com

Microbiological data

ClearKlens Bi-Spore SC working solution passes:

EN 13704: passes against *B. subtilis* in hard water (300 ppm as CaCO₃), no soil (0% bovine albumin) with a 5 minute contact time.

EN 13704: passes against *B. subtilis* in hard water (300 ppm as CaCO₃), low soil (0.03% bovine albumin) with a 10 minute contact time (norm is 1hour).

EN 1276: passes against *E. coli*, *P. aeruginosa*, *S. aureus* and *E. hirae* in hard water (300 ppm as CaCO₃), in low soil and high soil conditions (0.03 and 0.3% bovine albumin respectively) with a 5 minute contact time.

EN 1650: passes against *C. albicans* and *A. niger* in hard water (300 ppm as CaCO₃), in low soil conditions (0.03% bovine albumin respectively) with a 15 minute contact time.

EN 13697: passes against *E. coli*, *P. aeruginosa*, *S. aureus* and *E. hirae* in hard water (300 ppm as CaCO₃) in low soil conditions (0.03% bovine albumin) with a 5 minute contact time and passes against *C. albicans* in hard water (300 ppm as CaCO₃), in low soil conditions (0.03% bovine albumin) with a 15 minute contact time.

EN 14476: passes against Poliovirus Type 1 in distilled water under low soil conditions (0.03% bovine albumin) with a 1 minutes contact time.

EN 14476: passes against Murine Parvovirus in distilled water under low soil conditions (0.03% bovine albumin) with a 1 minutes contact time.

Full microbiological reports available on request.



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Available pack sizes

Pack size:

25 x (100 ml base + 100 ml activator)

Exists also as Ready to use solution with WFI:

4 x (4.9 l base + 100 ml activator)

10 x (950 ml base + 50 ml activator) – bottle screwable on a mop

Also available as non-sterile version:

25 x (100 ml base + 100 ml activator)