

B-SANYSAFE C[®]

The modern concentrated synthetic preparation for cold chemical disinfection intended for inpatient and outpatient use, totally water-soluble



TECHNICAL SHEET

DESCRIPTION

It performs an Exclusive action thanks to the properties of **Triadanol III** complex.

It destroys all microorganisms without damaging the constituent parts of the Device treated and the binding components (seals, mastics, welds, etc.).

It does not deviate the chemical and physical properties of materials, leaving the surface of the Device treated totally clean and without any residue and chemical element trapped.

Specifically tested on Optical Fiber instruments, also on cutting-edge instruments made of plastic material, it can be used in endoscope washing machines;

It does not contain **Peroxide**: therefore, it is perfect for cold chemical disinfection of the most delicate and valuable Devices;

It has 36-month stability/validity in its original unopened and appropriately stored package;

In conditions of use it is active for 15 days. Dilute it preferably with demineralised water;

It does not need to be activated because it is monocomponent;

The exhausted solution is over 94% biodegradable and disposable according to the legislation in force..

COMPOSITION

Active ingredients: **TRIADANOL[®] -3**.

Other components: alcohol, tetramethylammonium chloride, citrus fruit essential oil, co-formulants, distilled water q.s.

MECHANISM OF ACTION

Exclusive Synergic Action:

Thanks to its organic synthesis element, B-SANYSAFE C has a great stability and it acts in a way that in chemistry is defined "ideal solution", having non-deviant colligative properties: thus, it leaves the surface of the device treated totally clean, without any residue and chemical element trapped.

B-SANYSAFE C performs its disinfecting activity thanks to an exclusive action given by the properties of **TRIADANOL[®] -3**, which increases its action on the cell membrane and interrupts the chemiosmotic function of the lipoprotein cytoplasmic membrane.

INDICATIONS

It is intended for hospital use and for doctor's and dentist's offices. It is suitable for use in Endoscopy, Pulmonology, Urology, General and Laparoscopic Surgery, ORL, Dentistry, Arthroscopy, Gynecology, Neurosurgery, Anesthesia, Hemodynamics, Heart Surgery, Ophthalmology, Dialysis.

COMPATIBILITY

In mode of use, the B-SANYSAFE C preparation showed a great compatibility with the materials with which all the instruments and systems used in medical and surgical practice are made, it was specifically tested and resulted suitable for all optical fiber flexible devices, also of latest generation and in plastic material.

Studies:

- **G. Ortaggi- Chemistry Dep. "La Sapienza" University, Rome:** *Studio morfologico di microscopia elettronica a scansione (SEM, VP 1450) sulle componenti di strumenti termolabili flessibili trattate con B-SANYSAFE C*
- **D. Ferro et al. - Lab. CNR LiSA - ASSING:** *Studio morfometrico per la compatibilità di materiali costituenti lavaendoscopi;*
- **G. Ortaggi - Chemistry Dep. "La Sapienza" University, Rome:** *Il Studio morfologico di microscopia elettronica a scansione (SEM, VP 1450) sulle componenti di strumenti a fibre ottiche trattate con disinfettante chimico a freddo;*
- **Lab. CNR LiSA - ASSING:** *Studio morfometrico alla microscopia a scansione elettronica dei materiali costituenti lavaendoscopi;*
- **Lab. CNR LiSA - ASSING:** *Studio morfometrico alla microscopia a scansione elettronica delle superfici dei componenti del catetere endoscopico della Menfis Biomedics srl;*

Compatibility:

- **Lab. CNR LiSA - ASSING:** *Studio morfometrico alla microscopia a scansione elettronica delle superfici dei componenti del catetere endoscopico della Menfis Biomedics srl.*

MODE OF USE

It can be used both at room temperature and with preheated water, in manual or automatic mode. B-SANYSAFE C preparation disinfects in **10 minutes**.

PREPARATION:

IN MACHINE- respect the minimal dilution of 2.5% for disinfection and 1% for sanitisation and follow the instructions of the machine.

MANUAL- Introduce water into the washer, then pour the proper amount of disinfectant based on the dilution required. Respect the minimal dilution of 2.5% for disinfection and 1% for sanitisation.

Its efficacy against the most resistant Spore (*Bacillus Stereo-Thermophilus*) is assured. You can ask for a packaging suitable for the capacity of the circuit.

After opening the container, the product lasts for 60 days. The product used has to be replaced after 15 days.

INSTRUCTION OF USE

Set up a time of contact of 10 minutes

WARNINGS

The preparation has to be handled by qualified personnel, following appropriate safety rules and good hygiene practice rules. Keep out of reach of children. Store in a dry place at room temperature and away from heat (Range from +5° C a +40° C). The expiry date refers to the product in its original unopened and appropriately stored package.

SAFETY

The product does not require specific precautionary measures for people and the environment.

STABILITY AND VALIDITY

B-SANYSAFE C preparation is stable for 36 months in its original unopened and appropriately stored package at room temperature.

Studies:

- **FIS&DM Internal Laboratory:** *Analisi sulla stabilità del prodotto secondo lo schema "Tripartite ICH Guideline" e la NORMA UNI EN ISO 175:2010*

TOXICITY

B-SANYSAFE C preparation is not toxic.

Studies:

- **RTC – Research Toxicology Centre, Roma:** “B-SANYSAFE C (Diluted 1:10 in water) – Acute Dermal Irritation Study in Rabbits Final Report (RTC Study No: 74740);
- **RTC – Research Toxicology Centre, Roma:** Titolo dello Studio: “B-SANYSAFE C (Diluted 1:10 in water) – Acute Oral Toxicity Study in Rats (Fixed Dose Method) - Final Report (RTC Study No: 74750).

BIODEGRADABILITY

After use, the exhausted solutions are 94% biodegradable. Dispose them according to the legislation in force.

Studies:

- **ISIRIM – Istituto Superiore di Ricerca e Formazione sui Materiali Speciali per Tecnologie Avanzate:** Test di biodegradabilità o Test di Strum modificato.
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TRACEABILITY

The entire batch traceability, from the acceptance of raw materials to the distribution of the finished product, is carried out according to internal quality system procedures.

BACTERICIDAL ACTIVITY

- **EN 14561- Carrier test for the evaluation of bactericidal activity in the medical area**

Strains used:

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Results:

Time of contact: 5' - R \geq 5Log

- **EN 13727 - Test for the evaluation of bactericidal activity in the medical area**

Strains used:

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Results:
Time of contact: 5' - R ≥ 5 Logs

BACTERICIDAL – FUNGICIDAL ACTIVITY

Experimental protocol EX/02 – Certificate no. 02 EN 13697 – Test to determine bactericidal and fungicidal activity according to CEN TC/216 method EN 13697 Chemical disinfectants and antiseptics
– Quantitative surface test for the evaluation of bactericidal and fungicidal activity of chemical disinfectants – Test method without mechanical action and requirements (phase 2/step 2).

The Test showed complete compliance of B-SANYSAFE C to the parameters established, validating its **Bactericidal and Fungicidal activity**. At the end of the time set by the Regulation for every strain used, a **cfu growth = 0** was obtained.

FUNGICIDAL ACTIVITY

Experimental protocol EX/01 – Certificate no. 01 EN 1650 Test to determine fungicidal activity according to CEN TC/216 method EN 1650 Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants in presence of interfering substances – Test method and requirements.

The Test showed complete compliance of B-SANYSAFE C to the parameters established, validating its **Fungicidal activity**. At the end of the time set by the Regulation for every strain used, a **cfu growth = 0** was obtained.

- **EN 13624 – Quantitative suspension test in the medical area**

Strains used:
Candida albicans ATCC 10231
Aspergillus brasiliensis ATCC 16404

Results:
Time of contact: 5' - R ≥ 4 Logs

- **EN 14562 – Quantitative carrier test in the medical area**

Strains used:
Candida albicans ATCC 10231
Aspergillus brasiliensis ATCC 16404

Results:
Time of contact: 5' - R ≥ 4 Logs

MYCOBACTERICIDAL ACTIVITY

- **EN 14348 – Test for the evaluation of mycobactericidal activity in the medical area**

Strains used:

Mycobacterium avium ATCC 15769

Mycobacterium terrae ATCC 15755

Results:

Time of contact: 1' - R \geq 4 Logs

- **EN 14563 – Carrier test for the evaluation of mycobactericidal activity in the medical area**

Strains used:

Mycobacterium avium ATCC 15769

Mycobacterium terrae ATCC 15755

Results:

Time of contact: 5' - R \geq 4 Logs

The Test showed complete compliance of B-SANYSAFE C to the parameters established, validating its **Mycobactericidal** activity. At the end of the time set by the Regulation for every strain used, a **cfu growth = 0** was obtained.

VIRUCIDAL ACTIVITY

B-SANYSAFE C is a powerful broad spectrum antiviral agent, it is an antagonist of viral and retroviral evolution, and it is capable of killing viruses and blocking their replication factor by inhibiting RNases. It has lipophilic properties and, by fluorescent excitation, it causes an irreversible damage to the cell membrane.

Pisa Univ., Department of Experimental Pathology, Medical Biotechnology, Infectivology and Epidemiology – Retrovirus Center – Director Prof. Mauro Pistello – October 27, 2006 - Studi di efficacia Microbiologica e di Attività Virale. Analisi sulla capacità di B-SANYSAFE C di denaturare RNasi virali.

B-SANYSAFE C is active on viruses within 1 minute – The Study showed the ability to denature viral RNases and complete inactivation with **pfu growth = 0**

Microbiology and Virology Lab, Vita-Salute San Raffaele University, Milan - EN 14476:2005 Chemical disinfectants and antiseptics. Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 1)

In this study, a reduction of more than 4 Log₁₀ of Poliovirus 1 and Adenovirus 5 infection load was obtained using B-SANYSAFE C under clean conditions at the incubation time of 1 minute and under dirty conditions at the incubation time of 5 minutes.

Studies:

- M. Pistello: **Title of the Study: “Inibizione delle RNasi virali HIV, HCV” da parte del sale di sintesi Triadanol-3;**
- Prof. Massimo Clementi; Vita-Salute, San Raffaele University – Milan Università Vita-Salute, San Raffaele - Milano: **“Attività virucida della formulazione disinfettante (EN 14476:2005);**
- **EN 14476 – Virucidal activity test**
Strains used:
Poliovirus type 1
Adenovirus type 5
Murine Norovirus

Results:

Time of contact: 5' - R ≥ 4 Logs

STUDIES ON ENDOSCOPES

Microbiology and Virology Lab, Vita-Salute San Raffaele University, Milan - EN 14561:2006 Chemical disinfectants and antiseptics. Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area. Test method and requirements (phase 2, step 2).

In accordance with the procedure described by the European Standard 14561:2006 and the requirements identified by the same Standard, after the use of B-SANYSAFE C a reduction of 5 logs in bacterial counts under clean conditions, at 20 °C for 1 minute and under dirty conditions for 5 minutes was observed.

SIZES AND PACKAGES

BSSC5	B-SANYSAFE C	5 Lt tank
BSSC1	B-SANYSAFE C	1Lt bottle
BSSC2	B-SANYSAFE C	2Lt bottle

Industrial property

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N.B.: More information, studies in the literature and safety sheets are provided by the company only upon request. The company reserves the right to make updates and changes at any time.