

B-SANYSAFE SPRAY

Solution for high-level disinfection of
medical devices and surgical equipment



TECHINICAL DATA SHEET

DESCRIPTION

SANYSAFE SPRAY[®] is a modern and effective synthetic preparation ready to use for high- level cold chemical disinfection in hospital setting.

- Powerful disinfectant, cleaning and regenerating agent for surgical equipment and accessories which come into contact with patients.
- Exclusive action with a broad spectrum of activity (bacteria, yeasts, fungi, and viruses) and an **outstanding speed of disinfection**.
- No need to rinse off.
- Also effective in presence of organic matter.
- **It does not contain Peroxide**: therefore, it is perfect for high-level cold chemical disinfection of the most delicate and valuable Devices because it is not corrosive for materials and it is compatible with thermolabile instruments.
- The bath for high disinfection is active for **12 days**.
- It has **36-month** stability/validity in its original unopened and appropriately stored package.
- It does not need to be activated because it is monocomponent. **Neutral pH**.
- The exhausted solution is **over 94% biodegradable** and disposable according to the legislation in force.

COMPOSITION

Diphedac[®], Surfactant complex (composed of alkyl-dimethyl-benzyl ammonium chloride), Isopropyl alcohol, Essential oils.

MECHANISM OF ACTION

B SANYSAFE SPRAY[®] greatly weakens the surface tension of his carrier (water) so that the solution penetrates even in the most unreachable corners of the equipment to disinfect. Being in close contact with the bacterial mass, the solution spreads into the germs through capillary effects, poisoning the nucleus, irreversibly modifying the genetic material and causing death. It combines the alkylation activity with the removal of cell sulphydric groups without any chance of reactivation for fragments.

UNIQUE AND PECULIAR FEATURES

Unlike many products for high disinfection currently available on the market, **B SANYSAFE SPRAY[®]** does not show any risk of co- carcinogenicity, ensuring its totally safe use.

INDICATIONS

High level disinfection, cleaning of medical equipment:

It is suitable for all kinds of surgical and non-surgical instruments, medical equipment and devices, laboratories, laminar flow hoods, blood bank refrigerators, filters, accessories of systems for analysis.

B SANYSAFE SPRAY[®] combines two alcohols and an Adamantane- carboxylate salt in N,N dimethylphenylethylamine to increase the spectrum of activity and reduce the necessary time of contact. This original formula provides advantages in terms of efficacy and safety for medical equipment, medical devices used in intensive care units, emergency rooms, thoracic surgery wards and hemodynamic wards. It ensures a quick and effective high-level cold disinfection.

INCOMPATIBILITY

Do not mix the product with substances other than water.

MODE OF USE

Cold disinfection and cleansing of medical instruments and equipment: Time of contact 5 minutes – Bath active for 12 days

For a dirty device, carry out a preliminary cleansing and soak completely the surface to treat. Remove the device with sterile technique. For devices that have to be stored, bathe the instrument to clean without rinsing off and dry with a sterile gauze. Before reusing the device, use a gauze soaked in purified water.

The bath is active for 12 days.

The preparation has to be used as it is keeping to the schedule.

RESIDUE AFTER RINSING

The gas chromatography performed on the first rinsing waters found over 94% of active ingredient, showing that the ingredient does not saturate materials.

BIODEGRADABILITY

Perfectly biodegradable according to OECD 301 B.

STABILITY

A study of active ingredient stability and biological activity according to EN 13610 reports a **36-month validity**.

Study:

Department of Chemistry, "La Sapienza" University – Rome: Title of the study: **Studio di Stabilità del dispositivo medico disinfettante ad alto livello classe IIa Adantium Plus**

TOXICITY

Low toxicity: (LD 50 rat oral: ~2.000 mg/kg).

Studies:

- RTC – Research Toxicology Centre, Rome:
Title of the Study: "B SANYSAFE SPRAY Plus – Acute dermal irritatio study in the rabbit – Final Report (RTC Study No: 8931-1).
- RTC – Research Toxicology Centre, Rome:
Title of the Study: "B SANYSAFE SPRAY – Assessment of cellular toxicity by agarose overlay – Final Report (RTC Study No: 14660-M-01677).
- RTC – Research Toxicology Centre, Rome:
Title of the Study: "B SANYSAFE SPRAY – Single dose oral toxicity study in the rat – Final Report (RTC Study No: 16880- 1).
- Pavan; Department of Experimental Medicine, "L'Aquila" University:
Title of the Study:
Prove di irritazione dermale acuta dopo applicazione di B SANYSAFE SPRAY (in ottemperanza alle norme descritte dalle OECD guidelines N° 404 e N° 410 ed ISO 10993).

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.

EN14885

The bibliography concerning the **B SANYSAFE SPRAY** array was updated in compliance with **EN14885** «Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics.», which indicates the tests to perform based on the specific field of use of the disinfectant.

CLINICAL VALIDATION

Assessment of in vitro antimicrobial activity of **B SANYSAFE SPRAY**[®] in the prevention of hospital-acquired infections: **B SANYSAFE SPRAY**[®] demonstrated an excellent antimicrobial activity; a reduction of >5 logarithms in 5 minutes of action time was observed in many strains usually present in hospitals, frequently associated with nosocomial infections.

BACTERICIDAL ACTIVITY

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

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Results:

Time of contact: 5' - R ≥ 5Logs

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

Used strains:

Pseudomonas aeruginosa ATCC 15442

Staphylococcus aureus ATCC 6538

Enterococcus hirae ATCC 10541

Results:

Time of contact: 5' - R ≥ 5Logs

VIRUCIDAL ACTIVITY

- **EN 14476 – Virucidal activity test**

Used strains:

Poliovirus type 1

Adenovirus type 5 Murine Norovirus

Results:

Time of contact: 5' - R ≥ 4 Logs

The formulation made with the active ingredient Diphedac[®] underwent a test of **virus inactivation** at ambient temperature in three minutes in presence of fetal bovine serum 5%: GLP studies conducted according to U.S. Environmental Protection Agency standards related to compound characterization and stability on the following viral cells:

- Human Coronavirus ATCC VR-740, Strain 229E - Herpes Simplex virus type ATCC VR734, Strain – Human Influenza A-type 1-Hepatitis C – B – Human Immunodeficiency virus type 1 (HIV).

Study Directory: Mary J. Miller – Douglas G. Anderson – Karen M. Ramm – Jennifer Palmen – Tonia Bevers

ATS LABS – Saint. Paul, MN 55120 – USA.

All formulations have complete

FUNGICIDAL ACTIVITY

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

Used strains:

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**

Used strains:

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**

Used strains:

Mycobacterium avium ATCC 15769 Mycobacterium terrae ATCC 15755

Results:

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

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

Used strains:

Mycobacterium avium ATCC 15769 Mycobacterium terrae ATCC 15755

Results:

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

SPORICIDAL ACTIVITY

- **EN 14347 - Test for the evaluation of sterilizing activity**

Used strains:

Bacillus Subtilis ATCC 6633

Results:

Time of contact: 10' - growth= 0 CFU

Based on experimental conditions and interpretation criteria provided by the European Standard EN 14347:2005, B SANYSAFE SPRAY® Plus showed sporicidal **activity within 10 minutes at 2.5% dilution and a spore abatement of 3 logs₁₀ at 0.5% dilution.**

WARNINGS

The European guidelines on dangerous preparations contained in the EC Directive 88/379 and the Italian Ministry of Health require some care in treating the product according to the following.

SIZES AND PACKAGES

500 ML Bottle - Code BSS5FP

1 LITER Bottle - Code BSS1FP

5 LITER Tank - Code BSS5T

Packages containing higher or lower amounts of product can be made upon request.

Industrial property

Manufactured by: FIS & DM S.r.l. – Str. di Sabbione, 27/A 05100 TERNI

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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.