

BACTRYL™ SPRAY | BACTRYL™ WIPES

Disinfectant and Cleaner



BACTRYL™ DISINFECTANT

Powerful disinfectant and surface cleaner, available in both spray and wipes

Ready-to-use cleaning and disinfecting agent with bactericidal, virucidal, fungicidal, yeasticidal and mycobactericidal properties on surfaces and on invasive and non-invasive medical devices. It is a class IIb Medical Device



Effective cleaning and disinfection

- Tested by two accredited laboratories and approved by independent experts^{1,2}
- Double action in one product, cleaning and disinfection, thanks to the combination of quaternary ammonium compounds and chlorhexidine
- Registered on the VAH-List of Disinfectants (The Association for Applied Hygiene, Germany)
- Have demonstrated complete inactivation of enveloped viruses such as MVA, BVDV, HIV, HBV, Coronavirus, and Influenza

Tested compatibility

- Compatible with a wide range of materials, including HDPE, Teflon, PVC, PET, silicone, neoprene rubber, and metals such as aluminum and stainless steel
- Can be used with invasive and non-invasive devices
- Gentle and safe for surfaces, Neutral pH



Safe for surfaces in medical, endoscopic, and dental facilities, including invasive and non-invasive devices, instruments, accessories and equipment.



Safe and easy to use

- Ready to use—just spray and wait, or spray and wipe for faster action
- Safe for operators, contains no carcinogenic, mutagenic, or toxic ingredients
- No bleach, no aldehydes, no phenols
- Broad application throughout your medical or dental site

Rapid and lasting action

- Disinfectant in 1 minute on bacteria, yeast and enveloped viruses (in compliance with EN 14885)
- Disinfectant in 30 seconds on bacteria and yeast if rubbed on with a towel/cloth (EN 16615)
- Fungicidal and Mycobactericidal activity between 2-10 minutes according to the stains

BACTRYL™ Disinfectant meets the relevant requirements of European Directives for a wide spectrum of action.

In compliance with EN 14885 and EN 16615 (surface disinfectant)

DISINFECTANT ACTIVITY	
ACTIVITY	STANDARD
Bactericidal*	EN 13727, EN 13697 <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>E. coli</i> , <i>Enterococcus hirae</i> , <i>Salmonella enterica typhimurium</i> , <i>Salmonella choleraesuis</i> , <i>Proteus mirabilis</i> .
Fungicidal/Yeasticidal*	EN 13624, EN 13697 <i>Candida albicans</i> , <i>Aspergillus niger</i> , <i>Trichophyton mentagrophytes</i>
Bactericidal/Yeasticidal	EN 16615 <i>Pseudomonas aeruginosa</i> ATCC 15442, <i>Staphylococcus aureus</i> ATCC 6538, <i>Enterococcus hirae</i> ATCC 10541, <i>Candida albicans</i> ATCC 10231
Mycobactericidal/ Tubercicidal	EN 14348 <i>M. smagmatis</i> , <i>M. avium</i> , <i>M. terrae</i>
Virucidal**	EN14476 (HIV, HBV, HCV) DVV/RKI (enveloped viruses)** BVDV, Vaccinia Virus Strain Ankara HIV, HBV, HCV e influenza viruses.

* Tested according to requirements and methods for VAH Certification of Chemical Disinfection procedures. VAH Listed.

** Validated in external lab in according to the Guideline of the Robert-Koch-Institute RKI (German Federal Health Authority) and the Deutsche Vereinigung zur Bekämpfung der Viruskrankungen DVV (German Registered Association for Combating Viral Diseases).

ORDERING INFORMATION		
PART NUMBER	DESCRIPTION	UNITS PER BOX
500046	Bactryl Spray, Bottle of 1000 ml	4 bottles
500047	Bactryl Wipes, Tube with 110 wipes	6 tubes

Bench tested and confirmed with two independent labs.

Tests performed in clean and dirty conditions.

Recommended for use with Cantel capital equipment.

Use with confidence on Cantel equipment such as: CLEANASCOPE™ System Carts and Trays, SURESTORE™ Endoscope Storage & Transportation, ENDODRY™ Drying and Storage System, ISA™ Automated Endoscope Reprocessor, ADVANTAGE PLUS™ Automated Endoscope Reprocessor, ADVANTAGE PLUS™ Pass-Thru Automated Endoscope Reprocessor, RAPIDAER™ Endoscope Reprocessor along with a wide range of other health care cleaning and disinfection applications.



THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, **only Cantel delivers the Complete Circle of Protection**, a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimize your success.

References

1. H.P. Werner. HygCen Germany. (2018, February). Test report SN 24115 of 2017-02-27.
2. F.A. Pitten. HygCen Germany. (2018, June). Test report PL 18-46 180615

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TO PLACE AN ORDER

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BACTRYL WIPES

Instructiuni de folosire

SOLUȚIE DE DETERGENT ȘI DEZINFECTANT PENTRU SUPRAFEȚE ȘI DISPOZITIVE MEDICALE INVAZIVE ȘI NEINVAZIVE

Descriere: Soluție de detergent și dezinfectant gata de utilizare, bactericid, virucid, levuricid, fungicid, microbactericid pentru suprafețe și dispozitive medicale invazive și neinvazive.

Compoziție: clorură de benzalconiu g <1 - Digluconat de clorhexidină g <1 - Isazone® g 0,001, coformulanți și apă purificată q.s. la 100 ml.

Proprietăți microbiologice: soluție de curățare și dezinfectie gata de utilizare pe suprafețe și dispozitive medicale în 30 de secunde (EN16615) și 1 minut (dezinfectie de suprafață EN14885).

BACTERICID, LEVURICID și VIRUCID (virusuri încapsulate): 1 minut. **FUNGICID și MICROBACTERICID:** 5 minute.

Mod de utilizare: După ce ați îmbrăcat echipamentele de protecție personală (DPI), ștergeți cu șervețelul suprafețele și dispozitivele medicale și așteptați timpul de contact prevăzut. Clătiți dispozitivele medicale înainte de utilizare dacă acest lucru este prevăzut.

Instrucțiuni de utilizare:

- 1) Scoateți capacul exterior și pe cel interior.
- 2) Scoateți colțul liber al primului șervețel din centrul rolei și introduceți-l în orificiul din mijlocul capacului.
- 3) Puneți capacul înapoi și scoateți șervețelul până când tăierea este evidențiată; desprindeți cu fermitate șervețelul, blocând următorul șervețel cu dopul din mijlocul capacului.

Avertizări: Pericol. Respectați timpii de contact afișați pe etichetă și în instrucțiunile de utilizare. Produsul trebuie manipulat de personal calificat, cu standarde de siguranță adecvate, în conformitate cu instrucțiunile de utilizare prevăzute și cu fișa de siguranță. Nu ingerați. Nu lăsați la îndemâna copiilor. Pentru uz spitalicesc, ambulatorii medicale și stomatologice. Data expirării se referă la produsul din ambalaj, depozitat corespunzător. Nu utilizați produsul după data de expirare.

(H) Indicații de pericol: (H22S): Lichid și vapori ușor inflamabili (H319). (H319): Provoacă leziuni oculare grave. (H412): Toxic pentru organismele acvatice, cu efecte pe termen lung.

(P) Sfaturi de precauție: (P210): A se ține departe de sursele de căldură, de suprafețele fierbinți, de scântei, de flăcări de libere sau de alte surse de aprindere. Nu fumați. P280 Purtați mănuși / protejați-vă ochii/ protejați-vă fața. (P305+P351+P338): ÎN CAZ DE CONTACT CU OCHII: clătiți bine timp de câteva minute. Scoateți lentilele de contact dacă este cazul și dacă se poate face cu ușurință acest lucru. Continuați să clătiți. (P337+P313): Dacă iritația oculară persistă, consultați un medic. (P273): A nu se arunca în mediul înconjurător. Depozitare: A se păstra la temperatura camerei, departe de sursele de căldură.

Conținut: 3 ml per șervețel. Un borcan conține 110 șervețele.

Data revizuirii: 11/2019 Număr de urgență: +39.069145399



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MEDICAL DEVICE class IIb
CODE CODE. ISAS/CE/45

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1. Device Name

Bactryl® Wipes

2. Qualitative and quantitative composition

Composition of the wetting solution

100 ml contain

Isazone®	g < 0.05
Benzalkonium chloride 50%	g < 1
Chlorhexidine digluconate 20%	g < 1
Co-formulants and purified water	q.s. to ml 100.00

Composition of wipes

TNT (non-woven fabric).

3. Product presentation

Bactryl® Wipes is a detergent, disinfecting product for cleaning and disinfection of surfaces and on invasive and non-invasive Medical Devices. It comes in the form of wipes soaked in a clear light blue solution.

The presence of Benzalkonium chloride gives a residual bacteriostatic effect.

The product is packed in labelled jars, labelled, containing 110 disposable wipes.

4. Activity and microbiological properties

Bactryl® Wipes is a detergent, disinfecting product with a broad spectrum of activity against gram +, gram- bacteria, fungi, yeast, mycobacteria and enveloped viruses. The association of Isazone® with Benzalkonium chloride and Chlorhexidine digluconate speeds up its action.

4.1. Activity and microbiological properties, according to UNI EN 14885:2019: "Application of European standards for chemical disinfectants and antiseptics"

Bactericidal Activity	
Method used	EN 13727: quantitative suspension test for the evaluation of bactericidal activity in medical area (Clean and Dirty condition) TEST BY HYGCEN (CBI = 10 ⁸ ufc/ml R ≥ 5 log)
Strains used	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538P; MRSA <i>Enterococcus hirae</i> ATCC 10541 <i>Proteus mirabilis</i> ATCC 14153
Result	contact time: 1' – reduction > 5 log on bacteria, in both Clean and Dirty condition
Method used	EN 13727: quantitative suspension test for the evaluation of bactericidal activity in medical area (Clean and Dirty condition) (CBI = 10 ⁸ ufc/ml R ≥ 5 log)
Strains used	<i>Salmonella enterica typhimurium</i> ATCC 13311 <i>Salmonella choleraesuis</i> ATCC 10708



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Result	contact time: 10' - reduction > 5 log on <i>Salmonella enterica typhimurium</i> ATCC 13311, <i>Salmonella choleraesuis</i> ATCC 10708, in both Clean and Dirty condition
Fungicidal Activity	
Method used	EN 13624: quantitative suspension test for the evaluation of fungicidal activity in medical area (Clean and Dirty condition) TEST BY HYGCEN (CMI = 10 ⁷ ufc/ml R ≥ 4 log)
Strains used	<i>Candida albicans</i> ATCC 10231
Result	contact time: 1' – reduction > 4 log on <i>Candida albicans</i> ATCC 10231, in both Clean and Dirty condition
Method used	EN 13624: quantitative suspension test for the evaluation of fungicidal activity in medical area (Clean and Dirty condition) (CMI = 10 ⁷ ufc/ml R ≥ 4 log)
Strains used	<i>Aspergillus niger</i> ATCC 16404 <i>Trichophyton mentagrophytes</i> ATCC 9533
Result	contact time: 5' – reduction > 4 log on <i>A. brasiliensis</i> (ex niger) ATCC 16404, in both Clean and Dirty condition contact time: 10' – reduction > 4 log on <i>Trichophyton mentagrophytes</i> ATCC 9533, in both Clean and Dirty condition
Bactericidal – Fungicidal activity on surfaces	
Method used	EN 13697: quantitative suspension test for the evaluation of bactericidal - fungicidal activity in the presence of interfering substances (Clean and Dirty condition) TEST BY HYGCEN (CMI = 10 ⁷ ufc/ml R ≥ 4 log for bacteria) (CMI = 10 ⁷ ufc/ml R ≥ 3 log for fungi)
Strains used	<i>Staphylococcus aureus</i> ATCC 6538P <i>Enterococcus hirae</i> ATCC 10541 <i>Escherichia coli</i> ATCC 10536 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Candida albicans</i> ATCC 10231
Result	contact time: 1' – reduction > 4 log for bacteria - reduction > 3 log for fungi in both Clean and Dirty condition
Method used	EN 13697: quantitative suspension test for the evaluation of bactericidal - fungicidal activity in the presence of interfering substances (Clean and Dirty condition) (CMI = 10 ⁷ ufc/ml R ≥ 4 log for bacteria) (CMI = 10 ⁷ ufc/ml R ≥ 3 log for fungi)
Strains used	<i>Salmonella enterica typhimurium</i> ATCC 13311 <i>Salmonella choleraesuis</i> ATCC 10708 <i>Aspergillus niger</i> ATCC 16404 <i>Trichophyton mentagrophytes</i> ATCC 9533
Result	contact time: 10' – reduction > 4 log for bacteria - reduction > 3 log for fungi in both Clean and Dirty condition



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Method used	EN 16615 Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2) CMI = 10^9 ufc/ml R ≥ 4 log for Bacteria cells, CMI= 10^8 for <i>C. albicans</i> ATCC 10231))
Strains used	<i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Candida albicans</i> ATCC 10231
Result	contact time: 30'' – reduction > 5 log for bacteria - reduction > 4 log for fungi in both Clean and Dirty condition
Virucidal Activity	
Method used	EN 14476 Quantitative suspension test for the evaluation of virucidal activity (Dirty condition) – Test performed at La Sapienza, University of Rome – Virology Dept. R ≥ 4 log
Strains used	HIV USUV surrogate for HCV VSV surrogate for HBV
Result	contact time: 1'- reduction of viral replication R $\geq 4,0$ log
Method used	EN 14476 Virucidal activity against enveloped virus - Quantitative test modified for HBV and HCV (non surrogate wild strains) for the evaluation of virucidal activity by molecular assay-real time PCR method – Test performed at La Sapienza, University of Rome – Virology Dept. (Reduction levels %)
Strains used	HBV, HCV
Result	HBV: 78% - 1' contact time HCV: 87% - 1' contact time
Method used	Quantitative suspension test according to the Guideline of the Robert-Koch-Institute RKI (German Federal Health Authority) and the Deutsche Vereinigung zur Bekämpfung der Viruserkrankungen DVV (German Registered Association for Combating Viral Diseases)
Strains used	BVDV-Vaccinia Virus Strain Ankara HIV, HBV,HCV e influenza viruses
Result	Effective against enveloped viruses: undiluted / 1 min
Mycobactericidal Activity	
Method used	EN 14348 quantitative suspension test for the evaluation of mycobactericidal activity against mycobacteria (Clean and Dirty condition) (CMI = 10^8 ufc/ml R ≥ 4 log)
Strains used	<i>Mycobacterium smegmatis</i> CIP 7326 <i>Mycobacterium avium</i> ATCC 15769 <i>Mycobacterium terrae</i> ATCC 15755



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Result	contact time: 2' – reduction > 4 log on <i>M. smegmatis</i> CIP 7326, in both Clean and Dirty condition
	contact time: 5' – reduction > 4 log on <i>Mycobacterium avium</i> ATCC 15769 and <i>Mycobacterium terrae</i> ATCC 15755, in both Clean and Dirty condition

LEGEND:

IBL/IML

= Initial bacterial load/initial microbial load

R

= Expected reduction of bacterial/microbial load

cfu

= colony-forming units

pfu

= plaque-forming units

5. Directions for use

Bactryl® Wipes is a ready-to-use cleaning and disinfecting solution with bactericidal, virucidal, fungicidal, yeasticidal and mycobactericidal action on Medical Devices, effective in 30 seconds (EN 16615) and 1 minute (EN 14885 disinfection for surfaces).

Directions for use: After putting on the Personal Protective Equipment (PPE), wipe surfaces and medical devices evenly with the wipe and wait for the expected contact time.
Rinse off the medical devices before use if expected.

Instructions for use:

- 1) Remove the lid and the protection plug.
- 2) Pull out the loose section of the wipe from the centre of the roll and insert it into the eyelet in the middle of the lid.
- 3) Fix the lid and pull out the wipe until you can see the pre-cut section; firmly tear off the wipe, locking the next wipe with the plug in the middle of the lid.

Compatibility: the solution is highly compatible with the materials constituent the medical devices and the main surfaces in hospitals and dental practice (including handles, lamps, chairs).

6. Toxicological Information

Acute toxicity

for benzalkonium chloride

DL₅₀oral rat: 400 mg/kg

- General effects

nausea and vomiting, if ingested in large quantities;

7. Warning

Warning: Hazard.



(H) Hazard statements:

H225 Liquid and vapors highly flammable.

H319 Causes severe eye irritation.

H412 Harmful to aquatic organisms with long-term effects.

(P) Prevention precautionary statements:

P210 Keep away from heat sources, hot surfaces, sparks, open flames or other ignition sources. Do not smoke.

P280 Wear protective gloves and eye protection/face protection.

P305+P351+P338 IF IN EYES: rinse continuously with water for several minutes. Remove contact lenses



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if present and easy to do. Continue rinsing.

P337+P313 If the eye irritation persists, seek medical advice.

P273 Do not dispose of it in the environment.

For use in hospitals, and medical and dental practice. The product should be used by qualified staff in compliance with effective safety regulations. Keep out of reach of children.

Keep in a dry place at room temperature, away from heat sources. The expiry date refers to the product stored properly, in original package. Do not use after expiration date.

8. Physical and chemical properties

Characteristics of the disinfecting solution:

aspect	clear liquid
odour	citrus light
colour	light blue
specific weight	0.95-1.05 g/cm ³
pH	5.5-7.5

Characteristics of the wipe:

appearance	nonwoven, white, translucent fabric
dimensions	cm 14 x 25 ; (110 wipes)

9. Quality checks

The company operates under a fully certified Quality Management System as per UNI EN ISO 9001 - EN 13485.

10. Shelf-life

24 months for the product properly stored in original packaging.

11. Storage conditions

Keep in a dry place at room temperature, away from heat sources.

12. Type and capacity of containers

The jars are made of high density polyethylene (HDPE), white pigmented; the protective caps and the lids are made of polyethylene (PE).

The jars are further packed in a cardboard box containing 6 jars.

13. Name and address of the holder of the certification

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14. Compilation date:

Ed.	Rev.	Date	STATUS AND REASON OF REVISIONS
1	0	25.06.2019	Change of Notified Body (CE 0051)



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	1	28.11.2019	Revision of paragraphs 3, 4 and 5 to specify the action on surfaces. Revision of paragraph 4.1 for updating the applied standards and for updating the edition of the UNI EN 14885: 2019 standard.
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