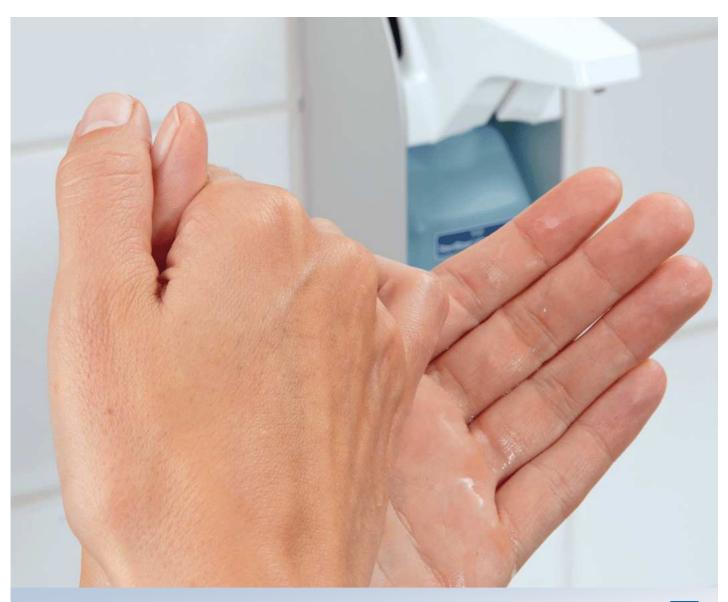


Very good skin tolerance. Comprehensively active against enveloped viruses. For operating theatres and wards.

# Sterillium® classic pure

The classic among rub-in hand disinfectants. Colourant- and fragrance-free. For hygienic and surgical hand disinfection.



Research for infection protection. www.bode-science-center.com



### Sterillium® classic pure

#### **Product properties**

- colourant- and fragrance-free
- possesses an excellent immediate effect
- provides very good residual effect
- excellent skin tolerability even with long-term use

#### Composition

Active ingredients in 100g: Propan-2-ol 45.0 g, propan-1-ol 30.0 g, mecetronium etilsulfate 0.2 g. Other ingredients: Glycerol 85 %, tetradecan-1-ol, purified water.

#### Microbiology

- bactericidal
- veasticidal
- tuberculocidal (Mycobacterium terrae)
- mycobactericidal
- virucidal against enveloped viruses (incl. HBV, HIV, HCV)
- adeno-, polyoma- and rotaviruses

#### Areas of application

Sterillium® classic pure is used as readyto-use alcohol-based rub-in product independently of water and washbasin in all areas of health care and industry where hygiene is important as well as in home dialysis and when travelling to prevent infections. Areas of application in detail:

For hygienic and surgical disinfection in health care:

- in inpatient facilities and functional areas such as operating theatres. intensive care units and infection departments
- in treatment rooms and outpatient departments
- in ambulances
- in laboratories and domestic services departments
- in hospital and canteen kitchens
- by emergency medical services
- in medical practices of all disciplines
- in home care of patients, elderly and
- for home dialysis

#### **Directions for use**

Sterillium® classic pure is rubbed undiluted into the dry hands; be sure that the hands are completely covered during the application time. Keep special attention to fingertips and thumbs. The product should be applied with an easy-to-use dispenser which is ideally elbow-operated.

For these dispensers, BODE offers single use product containers for most hygienic preconditions.

- hygienic hand disinfection: 30 seconds
- surgical hand disinfection: 1.5 minutes

Use disinfectants safely. Always read the label and product information before use.

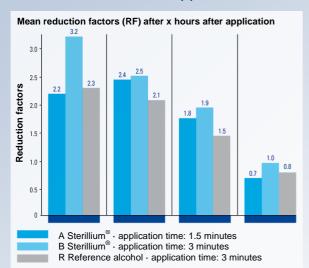
#### Compatibility with care products

The efficacy of Sterillium® classic pure is not influenced by the prior use of selected BODE hand care products.

Hygienic hand disinfection acc. to EN 1500 after use of Baktolan® lotion, Baktolan<sup>®</sup> balm and any other Baktolan<sup>®</sup> products

### Surgical hand disinfection within 1.5 minutes

In 2005, a study for the first time investigated the efficacy of the alcohol-based hand disinfectant Sterillium® for surgical hand disinfection with different application times (3, 2, 1.5 and 1 minute) in comparison with the 3-minute reference treatment in accordance with EN 12791 (1).



At any point in time, Sterillium® with application times of 1.5 and 3 minutes was at least as effective as the reference treatment. Also, its bacterial colonisation rate approximately corresponded to the reference alcohol.

Even with an exposure time of 1.5 minutes only, Sterillium<sup>®</sup>'s immediate and sustained effect is still superior to the 3-minute reference procedure.

Further studies have confirmed the efficacy, even with additional application to forearms and elbows (2, 3). The Federal Institute for Drugs and Medical Devices (BfArM) authorised the reduced application time in 2005. Since 2007, the Association for Applied Hygiene (VAH) certifies surgical hand disinfection procedures with exposure times below the previously approved minimum application time of 3 minutes.

Another study (4) with Sterillium® could proof that an exposure time of only 1.5 minutes does not influence the long-term effect of surgical hand disinfection. After 6 hours under the glove, Sterillium®'s colonisation rate was as low as the rate of the reference procedure with a 3-minute application time.

The exposure time of 1.5 minutes applies to the complete Sterillium<sup>®</sup> range of products and - depending on the preparation - meanwhile has become standard. The advantages include less consumption and, according to a study, time savings of approx. 1,000 working hours per year (5).

- 1 Kampf G, Ostermeyer C, Heeg P. Surgical hand disinfection with a propanol-based hand rub: equivalence of shorter application times. J Hosp Infect. 2005 Apr; 59(4):304-10.
  2 Suchomel M., Gnant G., Weinlich M., Rotter M. Surgical hand disinfection using alcohol: the effects of alcohol type, mode and duration of application. J Hosp Infect. 2009 Mar; 71(3):228-33.
  3 Kampf G, Ostermeyer C, Heeg P, Paulson D. Evaluation of two methods of determining the efficacies of two alcohol-based hand rubs for surgical hand antisepsis. Appl. Environ. Microbiol. 2006; 72:3856-3861.
  4 Rotter M L, Kampf G, Suchomel M, Kundi, M Long-term effect of a 1.5 minute surgical hand the prograph hand effect.

- Strong elimine and rub with a propanol-based product on the resident hand flora Journal of Hospital Infection, Volume 66, issue 1 (May, 2007), p. 84-85.
   Kampf G, Voss A, Widmer AF.Die chirurgische Händedesinfektion zwischen Tradition und Fortschritt Hyg Med 2006; 31 [7+8]: 316–321





## Sterillium® classic pure

#### **Proven efficacy**

<b>Bacteria</b> and fur	ngi		
EN Phase 2 / Step 2	Efficacy according to EN Phase 2 / Step 2	Hygienic Hand Disinfection (EN 1500)	30 sec.
Priase 27 Step 2	(Practical tests)	Surgical Hand Disinfection (EN 12791)	1.5 min.
EN	Appraised efficacy according to EN	Bactericidal (EN 13727)	15 sec.
Phase 2 / Step 1	Phase 2 / Step 1	Yeasticidal (EN 13624)	15 sec.
rnase 27 step 1	(suspension tests)	Tuberculocidal (EN 14348)	30 sec.
		Mycobactericidal (EN 14348)	30 sec.
EN	Appraisal according to EN Phase 1	Bactericidal (EN 1040)	15 sec.
Phase 1	(basic tests / suspension tets) without contamination; does not define the applicability of a product for a specific purpose	Yeasticidal (EN 1275)	15 sec.
VAH	Certified Application Recommendations for Hygienic Hand Disinfection from the Association for Applied Hygiene (VAH). Based on suspension and practical tests.	Bactericidal / Yeasticidal	30 sec.
	Certified Application Recommendations for Surgical Hand Disinfection from the VAH. Based on suspension and practical tests.	Bactericidal / Yeasticidal	1.5 min.
DGHM	Appraised efficacy against bacteria	MRSA / EHEC	30 sec.
2011111	(in accordance with the German Society of Hygiene and Microbiology [DGHM]); within the certified bactericidal efficacy	Listeria / Salmonella	15 sec.
RKI	Recognized substance for decontamination according to §18 IfSG (Robert Koch-Institut [RKI])	Area A - vegetative bacteria; incl. mycobacteria (use twice for Tb)	30 sec.
ASTM	Appraised efficacy in compliance with American Standard Test	Bactericidal (FDA) Yeasticidal (FDA)	30 sec. 30 sec.
Virusos	Methods (ASTM)	,	
Viruses	Efficiency and the state of the	A 1 (	
EN Phase 2/Step 1	Efficacy according to EN Phase 2 / Step 1 (suspension tests)	Adenovirus (EN 14476)	1 min.
DVV	Efficacy against viruses (German Society for the Control of Viral Diseases [DVV])	Virucidal against enveloped viruses (incl. HBV, HIV, HCV)	15 sec.
DVV	Appraised efficacy against enveloped viruses (in accordance with DVV)	Influenza-A-Virus (avian)	15 sec.
		Influenza-A-Virus (human)	15 sec.
		Herpes simplex Virus type 1 and 2	15 sec.
		SARS-CoV	30 sec.
DVV	Appraised efficacy against non-	Adenovirus	1 min.
	enveloped viruses (DVV)	Polyomavirus	5 min.
DVV	Appraised efficacy against enveloped viruses (DVV)	Rotavirus	15 sec.
Skin Disinfectio	n		
EN	Appraised according to Phase	Bactericidal (EN 13727)	15 sec.
Phase 2/Step 1	2/Step1 (suspension tests)	Yeasticidal (EN 13624)	15 sec.
VAH	Certified Application Recommendations for prophylactic skin disinfection from the Association of Applied Hygiene (VAH). Based on suspension and practical tests For skin low and rich in sebaceous glands	prior to injections and punctures	15 sec.
		Bactericidal/Yeasticidal skin low in sebaceous glands prior to punctures of joints, body cavitites, hollow organs und before surgical procedures	1 min.
		Bactericidal/Yeasticidal skin rich in sebaceous glands before all procedures	10 min.

#### Listing

- List of the Robert Koch-Institute (RKI)

  Effect area A
- List of disinfectants of the Association for Applied Hygiene (former DGHM list)
- IHO virucidal list

#### Chemical-physical data

Appearance transparent, colourless

■ Density (20 °C) approx. 0.85g/cm<sup>3</sup>

■ pH-value 50 % (v/v) approx. 8.3

Flashpoint

(acc. to DIN 51755) 23 ℃

#### **Stability**

After opening

 in tightly closed container or with pre-installed pump, dosing pump,

Eurodispenser 2, 3, 3000: 12 months ■ other dispensers: 6 months

#### **Publications**

#### Hygienic hand disinfection

H. Pietsch: "Hand antiseptics: rubs versus scrubs. Alcoholic solution versus alcoholic gels." Journal of Hospital Infection (2001) 48 Suppl. A: S33-S36.

A. Kramer, P. Rudolph, G. Kampf, D. Pittet. Limited efficacy of alcohol-based hand gels. The Lancet (2002) 359: 1489-1490.

G. Kampf, B. Meyer, P. Goroncy-Bermes. Comparison of two test methods for the determination of sufficient antimicrobial efficacy of three different alcohol-based hand rubs for hygienic hand disinfection. Journal of Hospital Infection (2003) 55: 220-225.

#### Surgical hand disinfection

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M.L. Rotter, G. Kampf, M. Suchomel, M. Kundi: "Long-term effect of a 1.5 minute surgical hand rub with a propanol-based product on the resident hand flora." Journal of Hospital Infection (2007) 66: 84-85.

M.G. Marchetti, G. Kampf, G. Finzi, G. Salvatorelli: "Evaluation of the bactericidal effect of five products for surgical hand disinfection according to prEN 12054 and prEN 12791." Journal of Hospital Infection (2003) 54: 63–67.

N.-O. Hübner, G. Kampf, P. Kamp, T. Kohlmann, A. Kramer: "Does a preceding hand wash and drying time after surgical hand disinfection influence the efficacy of a propanol-based hand rub?" BMC Microbiology (2006) 6: 57.

G. Kampf, C. Ostermeyer, T. Kohlmann. Bacterial population kinetics on hands during 2 consecutive surgical hand disinfection procedures. American Journal of Infection Control (2008) 36: 369-374.

G. Kac, E.Masmejean, M. Gueneret, A. Rodi, S.Peyrard, I. Podglajen: "Bactericidal efficacy of a 1.5 min surgical hand-rubbing protocol under in- use conditions." Journal of Hospital Infection (2009) 72, 135-139.

M.Suchomel, G.Gnant, M. Weinlich, M.Rotter: "Surgical hand disinfection using alcohol: ithe effects of alcohol type, mode and duration of application." Journal of Hospital Infection (209) 71, 228-233.



#### **Publications**

#### ■ Microbiological activities

- G. Kampf, R. Jarosch, H. Rüden. Wirksamkeit alkoholischer Händedesinfektionsmittel gegenüber Methicillin-resistenten Staphylococcus aureus (MRSA). Der Chirurg (1997) 68:
- G. Kampf, M. Höfer, C. Wendt. Efficacy of hand disinfectants against vancomycin-resistant enterococci in vitro. Journal of Hospital Infection (1999) 42: 143-150.
- G. Kampf, A. Hollingsworth: "Vality of the four European test trains of prEN 12054 for the determination of comprehensive bactericidal activity of an alcohol-based hand rub." Journal of Hospital Infection (2003) 55: 226-231.
- E. Martró, A. Hernández, J. Ariza, M.A. Domí nguez, L. Matas, M.J. Argerich, R. Martin, V. Ausina:" Assessment of Acinetobacter baumannii susceptibility to antiseptics and disinfectants." Journal of Hospital Infection (2003) 55: 39–46.
- H.F. Rabenau, G. Kampf, J. Cinatl, H.W. Doerr: "Efficacy of various disinfectants against SARS coronavirus." Journal of Hospital Infection (2005) 61: 107–111.
- G. Kampf, J. Steinmann, H. Rabenau, C. Payan. Suitability of vaccinia virus and bovine viral diarrhea virus (BVDV) for determining activities of three commonly-used alcoholbased hand rubs against enveloped viruses. BMC Infectious Diseases (2007) 7: 5.

#### Skin tolerability

- G. Sauermann, O. Proske, R. Keyhani, M.-C. Leneveu, H. Pietsch, B. Rohde. Skin tolerance of Sterillium and Hibiscrub: A comparative clinical trial. Hygiene + Medizin (1995) 20: 184-189.
- G. Kampf, M. Muscatiello: "Dermal tolerance of Sterillium, a propanol-based hand rub." Journal of Hospital Infection (2003) 55: 295–298.
- G. Kampf, W. Wigger-Alberti, K.-P. Wilhelm. Do atopics tolerate alcohol-based hand rubs? A prospective, controlled, randomized double-blind clinical trial. Acta Dermato-Venereologica (2006) 86: 140-143.
- R. Girard, E. Bousquet, E. Carré, et al. Tolerance and acceptability of 14 surgical and hygienic alcohol-based hand rubs. Journal of Hospital Infection (2006) 63: 281-288.
- F. Barbut, E. Maury, L. Goldwirt, et al. Comparison of the antibacterial efficacy and acceptability of an alcohol-based hand rinse with two alcohol-based hand gels during routine patient care. Journal of Hospital Infection (2007) 66: 167-173.

#### others

- G. Kampf, C. McDonald, C. Ostermeyer. Bacterial in-use contamination of an alcohol-based hand rub under accelerated test conditions. Journal of Hospital Infection (2005) 59: 271-272.
- G. Kampf, M. Reichel, Y. Feil, S. Eggerstedt, P.-M. Kaulfers. Influence of rub-in technique on required application time and hand coverage in hygienic hand disinfection. BMC Infectious Diseases (2008) 8: 149.



#### **Presentation**

100 ml bottle, 500 ml bottle, 1 litre bottle, 5 litre canister

Note: The recommendations regarding our preparations are based on scientific tests and are given in good faith. More detailed recommendations, e.g. regarding material compatibility, are only possible in particular cases. Our recommendations are without obligation and do not constitute a warranty. They do not preclude a company's own testing for the intended purposes and processes. In this respect we cannot accept any liability. This complies with our general conditions of sale and supply.

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#### Better compliance through good skin compatibility

Introducing Sterillium® to a medical intensive care unit (MICU) as alternative to washing increased compliance with hand disinfection by almost 20 per cent. These results were attributed to Sterillium®s good skin tolerability, even with repeated application.

Source: Maury E, et al. Availability of an alcohol solution can improve hand disinfection compliance in an intensive care unit. Am J. Respir. Crit. Care Med., 2000, 162: 324-7.

Research for infection protection.

