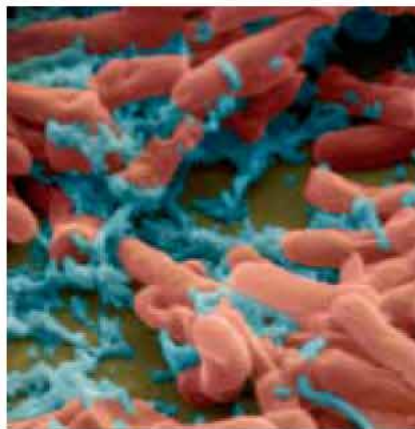


Sterillium® Rub

Waterless, Brushless Surgical Hand Antisepsis



Learn more about Europe's no. 1 brand with more than 40 years of experience.



Sterillium® Rub

Comprehensive and reliable

The aim of surgical hand antisepsis is the reduction of resident microorganisms and the elimination of transient microorganisms from the surgical team's hands for the duration of an operation. A procedure that does not significantly reduce the resident flora at the beginning of an operation or that does not keep the microbial release from the hands under baseline until the end of an operation is inadequate.

As many as three tests confirmed Sterillium® Rub's extremely effective and reliable performance: two tests according to FDA (Time Kill study and Tentative Final Monograph for Health Care Antiseptic Drug Products) and one European test in compliance with the European norm prEN 12791 for surgical hand antisepsis (1) – with the result that Sterillium® Rub meets the relevant international efficacy specifications.

Tests according to FDA

Antimicrobial effectiveness – In Vitro Time Kill Study

In Time Kill Studies the antiseptic tested is exposed to diverse microorganisms, including VRE and MRSA. After various contact times the remaining amount of bacteria is determined.

In such an independent Time Kill Study, Sterillium® Rub was challenged with 44 different microorganisms:



*Log₁₀ (logarithm) stands for a 10-fold or 90% reduction in numbers of recoverable bacteria. Another way to look at it is: 1 log₁₀ reduction reduces the number of bacteria by 90%. This means, for example, that 100 bacteria would be reduced to 10.

In Vitro Time Kill Study

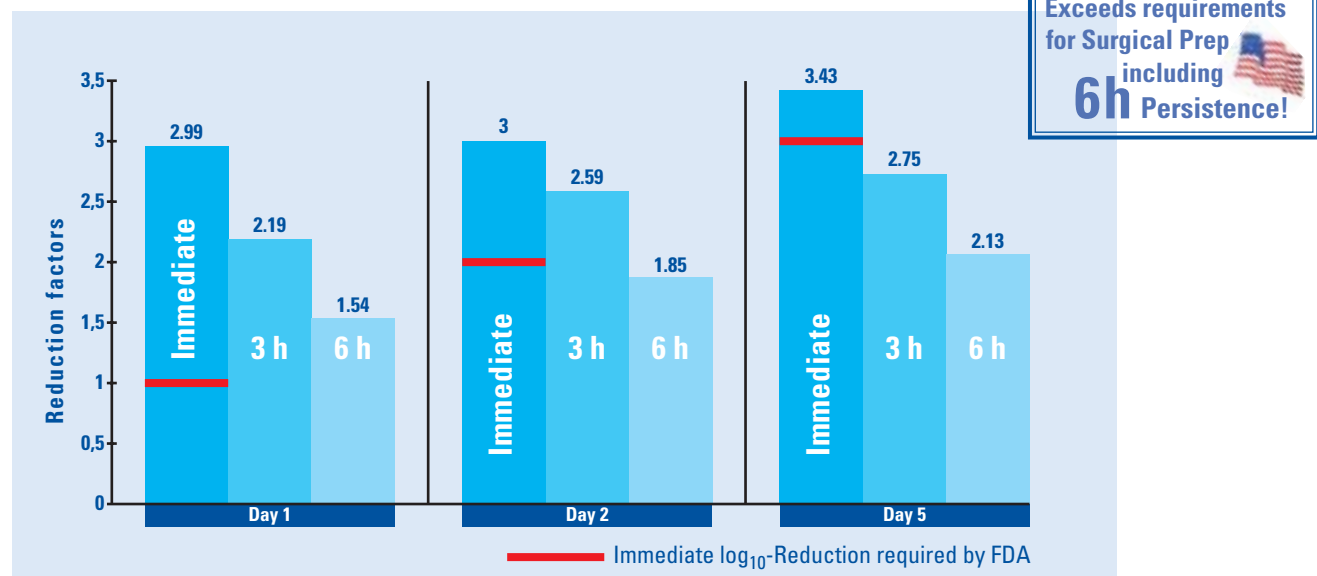
Challenge Microorganism	Reduction in 15 seconds	
	Log ₁₀ *	%
Acinetobacter baumannii (ATCC 19606)	5.62	99.99976
Acinetobacter lwoffii (ATCC 15309)	5.69	99.9998
Bacteroides fragilis (ATCC 25285)	6.02	99.9999
Burkholderia cepacia (ATCC 25416)	5.65	99.99978
Candida albicans (ATCC 10231)	5.97	99.99989
Clostridium difficile (ATCC 9689)	6.02	99.9999
Enterobacter aerogenes (ATCC 13048)	5.74	99.99982
Enterobacter cloacae (ATCC 1347)	5.70	99.9998
Enterococcus faecalis (ATCC 29212)	6.95	99.99999
Enterococcus faecalis (VRE) (CI 99165)	6.04	99.99991
Enterococcus faecium (ATCC 19434)	6.94	99.99999
Enterococcus faecium (VRE) (CI 99164)	5.98	99.9999
Escherichia coli (ATCC 11229)	5.82	99.99985
Escherichia coli (ATCC 25922)	5.82	99.99985
Escherichia coli (O157:H7) (CI 99166)	6.02	99.9999
Haemophilus influenzae (ATCC 19418)	6.97	99.99999
Klebsiella oxytoca (ATCC 43165)	6.00	99.9999
Klebsiella pneumoniae (ATCC 11296)	5.90	99.99987
Listeria monocytogenes (ATCC 7644)	6.63	99.99998
Micrococcus luteus (ATCC 7468)	5.70	99.9998
Mycobacterium tuberculosis (ATCC 27294)	6.04	99.99991
Mycobacterium tuberculosis (MDR) (CI 99282)	6.86	99.99999
Mycobacterium tuberculosis (MDR) (CI 99448)	6.86	99.99999
Proteus mirabilis (ATCC 7002)	5.86	99.99986
Pseudomonas aeruginosa (ATCC 15442)	5.94	99.99989
Pseudomonas aeruginosa (ATCC 27853)	5.81	99.99985
Salmonella enteritidis (ATCC 13076)	6.00	99.9999
Salmonella typhimurium (ATCC 13311)	5.91	99.99988
Serratia marcescens (ATCC 14756)	5.88	99.99987
Shigella sonnei (ATCC 11060)	5.51	99.99969
Staphylococcus aureus (ATCC 29213)	6.00	99.9999
Staphylococcus aureus (ATCC 6538)	6.00	99.9999
Staphylococcus aureus (CI 99286)	6.53	99.99997
Staphylococcus aureus (MRSA) (ATCC 33592)	6.02	99.9999
Staphylococcus aureus (MRSA) (CI 99161)	6.01	99.9999
Staphylococcus epidermidis (ATCC 12228)	6.00	99.9999
Staphylococcus epidermidis (CI 99288)	6.08	99.99992
Staphylococcus haemolyticus (ATCC 29970)	5.63	99.99977
Staphylococcus hominis (ATCC 27844)	5.64	99.99977
Staphylococcus saprophyticus (ATCC 15305)	5.66	99.99978
Streptococcus pneumoniae (ATCC 6303)	6.00	99.9999
Streptococcus pneumoniae (PRSP) (CI 99192)	6.70	99.99998
Streptococcus pneumoniae (PRSP) (CI 99449)	6.70	99.99998
Streptococcus pyogenes (ATCC 19615)	6.10	99.99992



Tentative Final Monograph for Health Care Antiseptic Drug Products (TFM)

The TFM minimum performance criteria for surgical hand antisepsis are a 1-log (90%) reduction after 1 minute on day 1, a 2-log (99%) reduction after 1 minute

on day 2, and a 3-log (99.9%) reduction after 1 minute on day 5. Moreover, the bacterial counts shall not exceed baseline within 6 hours on days 1, 2 and 5. Beyond these minimum requirements, Sterillium® Rub's effect was also tested after 3 hours – the average length of surgeries (2).



At all points in time Sterillium® Rub (80% Ethanol w/w) meets and yet exceeds the TFM requirements for surgical hand antisepsis – even with an application time as short as 2 minutes. Data on file.

Proven virucidal activity

In contrast to bacteria viruses possess a very variable chemo-resistance. As viruses are responsible for 5% of all nosocomial infections (3), the antiseptic's efficacy

against viruses is very important. Several tests confirmed Sterillium® Rub's distinguished activity against viruses:

Virus	Time	Log ₁₀ reduction	%	Test method
Adeno virus	2 min	2.50	99.683772	Suspension test
BVDV surr. for HCV	30 sec	4.00	99.99	Suspension test following BGA/DVV
FCV, surr. for Norovirus	30 sec	1.34	95.429118	In vivo test, ASTM E 1838-02
HBV	30 sec	3.00	99.9	Suspension test under dirty conditions, modification of ASTM E 1052
Herpes simplex virus type I	30 sec	4.75	99.998222	Suspension test
HIV	30 sec	3.50	99.968377	Suspension test
Influenza A virus	30 sec	5.75	99.999822	Suspension test
Polio virus	60 sec	4.75	99.998222	Suspension test
Rhino virus	2 min	4.50	99.996838	Suspension test
Rota virus	30 sec	5.50	99.999684	Suspension test
RSV	30 sec	3.75	99.982217	Suspension test
SARS -Coronavirus	30 sec	5.50	99.999684	Suspension test under dirty conditions (5)
Coronavirus type 229	30 sec	3.00	99.9	Fingerpad test
Vaccinia virus	30 sec	5.50	99.999684	Suspension test under dirty conditions, modification of ASTM E 1052



Sterillium® Rub

Meeting another challenge

All above mentioned test results show how effective Sterillium® Rub is. But what does the comparison to a

surgical antiseptics product already available on the market look like? (4)

In vitro Time Kill Study

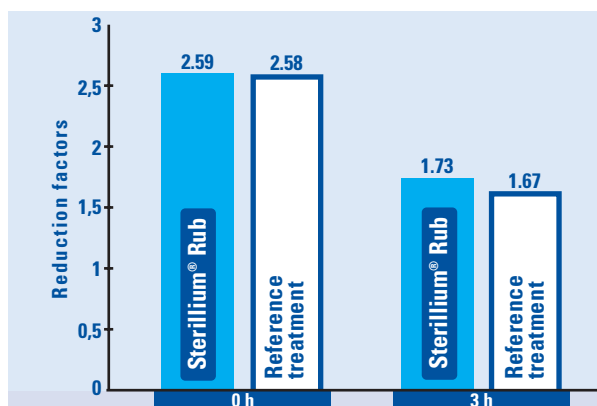
Microorganism	Sterillium® Rub		3M™ Avagard™ CHG	
	% Microbial Kill (15 seconds)	Log ₁₀ reduction (15 seconds)	% Microbial Kill (15 seconds)	Log ₁₀ reduction (15 seconds)
Staphylococcus aureus (ATCC 29213)	99.9999	6.00	99.99	4.00
Staphylococcus aureus (ATCC 6538)	99.9999	6.00	99.99	4.00
Staphylococcus aureus (MRSA) (ATC 33592)	99.9999	6.02	99.98	3.70
Escherichia coli (ATCC 11229)	99.99985	5.82	99.96	3.40
Escherichia coli (ATCC 25922)	99.99985	5.82	99.99	4.00
Pseudomonas aeruginosa (ATCC 15442)	99.99989	5.94	99.91	3.05
Pseudomonas aeruginosa (ATCC 27853)	99.99985	5.81	99.99	4.00
Serratia marcescens (ATCC 14756)	99.99987	5.88	99.99	4.00
Staphylococcus epidermidis (ATCC 12228)	99.9999	6.00	99.99	4.00
Micrococcus luteus (ATCC 7468)	99.9998	5.70	99.56	2.36
Enterococcus faecalis (ATCC 29212)	99.99999	6.95	99.95	3.30
Candida albicans (ATCC 10231)	99.99989	5.97	99.98	3.70

Sterillium® Rub has a strong and rapid bactericidal activity against gram-negative and gram-positive bacteria including antibiotic-resistant strains such as methicillin-resistant *S. aureus* (MRSA).

European test

In Europe alcohol-based hand rubs have commonly been used for surgical hand antiseptics for many years (5). Within the scope of the CEN Test Program for chemical antiseptics the test conditions for alcohol-based hand rubs have to meet practical requirements. This includes a sophisticated practical test in comparison to the reference alcohol n-propanol (60% by volume). In accordance with the European norm prEN 12791 the antiseptic should not be significantly less effective than the reference alcohol after 0 and 3 hours (Wilcoxon test). Result:

Sterillium® Rub is as effective (immediate and sustained effect) as the reference alcohol and meets the requirements for a surgical hand rub.



Mean reduction factor of Sterillium® Rub in comparison to the reference alcohol (60% n-propanol), 3 min.





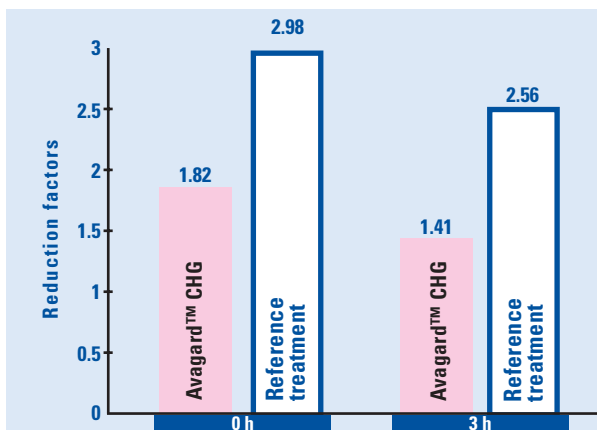
Going even further

The prEN 12791 test method is particularly suitable for the differentiation and comparison of various preparations based on different active agents (6). Knowing this, 3M™ Avagard™ was also tested.

Result: 3M™ Avagard™ applied for 3 minutes does not fulfill the efficacy requirements of the European norm prEN 12791 for surgical hand antisepsis (7).

Product	0 h		3 h	
	mean RF	p-value	mean RF	p-value
Sterillium® Rub	2.59	> 0.1	1.73	> 0.1
Reference treatment	2.58		1.67	
Avagard™ CHG	1.82	0.009	1.41	0.008
Reference treatment	2.98		2.56	

Mean reduction factor of Sterillium® Rub and Avagard™ CHG in comparison to the reference alcohol (60% n-propanol)

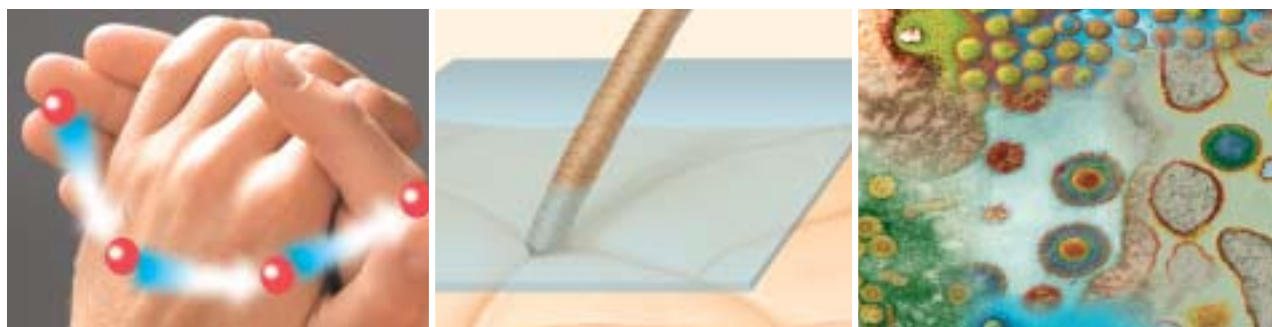


Bactericidal efficacy of Avagard™ CHG (3 min) in comparison to the reference alcohol (60% n-propanol; 3 min)

Everything under control. With Sterillium® Rub you have an extensive, effective hand antiseptic with a maximum of safety and comfort at hand.



Sterillium® Rub



No impact on your skin – big impact on bacteria.

Surgeons as well as medical and nursing staff have to disinfect their hands many times every day. Therefore, you know how important dermal tolerance is.

For the perpetuation of a natural barrier, skin needs to be soft, hydrated and pliable. Prolonged washing times and in particular the use of brushes destroy the protective function of the stratum corneum. Once the skin is affected it is more vulnerable to colonization of infectious agents. Here comes the good news: in the future you can do without any skin affecting brushes. Frequent hand antisepsis with the modern skin-friendly Sterillium® Rub – without washing – has a far less aggressive effect on the skin. It ensures a low rate of scaling and has skin-smoothing properties. Even with intensive long-term use.

It is often said that alcohols cause skin irritation or dry up the skin. However, alcohols do not alter the skin's natural pH, like antiseptic soaps do. Admittedly, alcohol dissolves the natural skin oils. But in contrast to hand cleansing, alcohol hand rubs do not rinse these oils off. They are rubbed back into the skin during the rub procedure. Thus the protective function of the stratum corneum can be maintained.

Additionally, Sterillium® Rub contains special emollients for improved skin tolerability and protection. When assembling the skin care substances and the potpourri of excipients for Sterillium® Rub, the attention was

turned to the restoration of the skin's moisture and lipid-content, a good spreadability and a comprehensive skin care.

In order to support Sterillium® Rub's gentle treatment, any wash with soap should be kept as short as possible.

The difference is noticeable.

The dermal tolerance of Sterillium® Rub was tested in an independent Repeated Insult Patch Test with the result that Sterillium® Rub did not demonstrate any potential for dermal irritation.



Repeated Insult Patch Test carried out with 53 panelists of different skin types: At all points in time Sterillium® Rub did not demonstrate any potential for eliciting either dermal irritation or sensitization.

With Sterillium® Rub, thorough hand antisepsis and skin protection go hand in hand. So the skin stays healthy too.



Excellent compatibility, better compliance

Non-compliance, i.e. not keeping to hygiene regulations, is still one of the main problems of hand-hygiene in health care. And also in the context of compliance with hand antisepsis skin tolerance plays a huge role. Understandably, as nobody wants to use something that inflicts damage. The main reason for poor compliance with hand antisepsis in hospitals is skin

irritation by hand-hygiene agents (8). As studies show, other deterrents to compliance include the amount of time required for hand antisepsis with water, scrub and brushes. The use of waterless, alcohol-based hand rubs instead of other antisepsis methods has been demonstrated to overcome all these barriers to compliance (9).

Sterillium® Rub Surgical Rub Method

Apply to clean, dry hands. For the first use of the day, use a nail pick. Hands should remain moist for entire application time, approximately 2 minutes.



Step 1

Dispense approximately 2 mL into hand, dip fingers of opposite hand into palm, working Sterillium® Rub under nails and into cuticles.



Step 2

Spread around the hand and lower 1/3 of the forearm.



Step 3

Repeat steps 1+2 with the other hand. Reapply Sterillium® Rub to the hands, paying particular attention to fingers, cuticles and interdigital spaces.



Step 4

Following application, rub hands until dry.



Sterillium® Rub

References

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- 2 Anonymous. Tentative final monograph for health care antiseptic drug products; proposed rule. Federal Register 1994, 59(116):31401-31452.
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- 4 3M Health Care, LIMS 8257. Taken from 3M's Brochure.
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- 9 Fendler E.J., Ali Y., Hammonda B.S., Lyons M.K., Kelley M.B., Vowell N.A., The impact of alcohol hand sanitizer use on infection rates in an extended care facility. American Journal of Infection Control 30: 226-233.

Warnings:

Flammable, keep away from fire or flame. For external use only.

Do not use in or near the eyes or on mucous membranes

When using this product and contact with the eyes occurs, flush immediately and thoroughly with water. **Discontinue use** if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.



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