



Surgical Hand Antisepsis with Sterillium® Rub

**Rapid, longlasting
and gentle to your skin**

Surgical Hand Antisepsis



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With publication of the WHO guidelines on hand hygiene in 2009, a new chapter of evidence-based medicine in infection control was opened worldwide. For decades, antiseptic soaps were preferred in many countries to alcohol-based hand rubs despite increasing evidence that the efficacy, dermal tolerance and effect on compliance are better with well-formulated alcohol-based hand rubs. A widespread shift towards alcohol-based hand rubs for surgical hand antisepsis will have many winners: patients will have a remarkably lower risk of a hospital-acquired infection, doctors and nurses will have a notably lower risk for skin irritation, and the whole healthcare system will face less costs overall for preventable hospital-acquired infection.

Especially for the pre-operative treatment of hands the choice of agents should be made with a lot of care. No treatment of hands has been shown to lead to surgical site infections despite wearing sterile gloves. That is why the chosen agent should be as effective as possible to reduce resident hand bacteria for the expected duration of the operation. Surgeons usually do not want to waste time. That is why treatment with the chosen agent should be as short as possible without making a compromise in efficacy. Wearing a surgical glove for hours is already a stress for the skin of the surgeon. That is why it is even more important to choose an agent for the pre-operative treatment of hands which does not add to this unavoidable stress for the skin.

Your patients and you deserve a justified choice of hand hygiene agent. It is in your hands...



Choosing progress

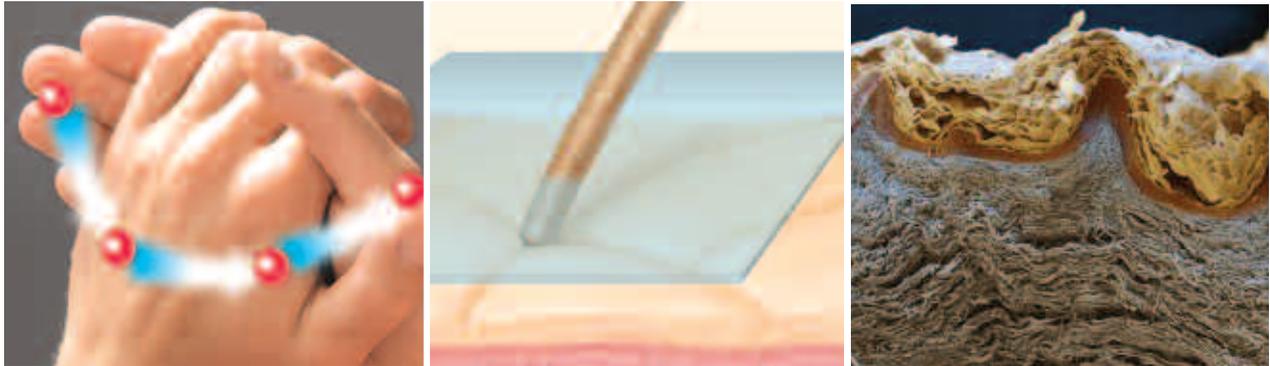
Underpinning its commitment to combat pathogenic organisms, BODE CHEMIE has been at the forefront of developing innovative products and even made medical history in 1965: Sterillium®, the first alcohol-based hand antiseptic, led to clearly improved infection prevention. Ready to use, greatly effective and extremely kind to the skin, Sterillium® was designed to meet the users' needs – setting off a success story.

Today Sterillium® is Europe's No.1 alcohol-based hand antiseptic. Sterillium®, stands as an example of our commitment to meet the demands of the future while providing the greatest benefit to our customers. Now, Sterillium® Rub adds to the high-performance of the brand. We invite you to learn more about the reasons for using one of the most reliable products for reducing the risk of infection in your OR.

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Easy on the skin



Little 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, dermal tolerance is critically important.

For the perpetuation of a natural barrier, skin needs to be soft, hydrated and pliable. Prolonged washing times and 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. Frequent hand antiseptics with the skin-friendly Sterillium® Rub – without washing – has a far less damaging impact 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 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 washing, 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 a proprietary blend of emollients for improved skin condition and moisture content. When developing the formula for Sterillium® Rub, attention was paid to the maintenance of the skin's moisture and lipid-content, ease of application and comprehensive skin care.

Excellent compatibility, better compliance

Not following appropriate hand hygiene recommendations is still one of the main factors of poor hand hygiene compliance. And in the context of compliance with hand antiseptics, skin tolerance plays a huge role. The main reason for poor compliance with hand antiseptics in hospitals is due to skin irritation by hand hygiene agents (1). As studies show, other deterrents to compliance include the amount of time required for hand antiseptics with water, scrub and brushes. The use of waterless, alcohol-based hand rubs instead of other antiseptics methods has been demonstrated to help to overcome these barriers to compliance (2).

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. (3)

**With Sterillium® Rub thorough
hand antiseptics and skin
protection go hand in hand.
So the skin stays healthy.**

Broad spectrum of efficacy

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 scrub-in 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.

Tests have 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 EN 12791 for surgical hand antisepsis (4) – with the result that **Sterillium® Rub meets the relevant US FDA's TFM and 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

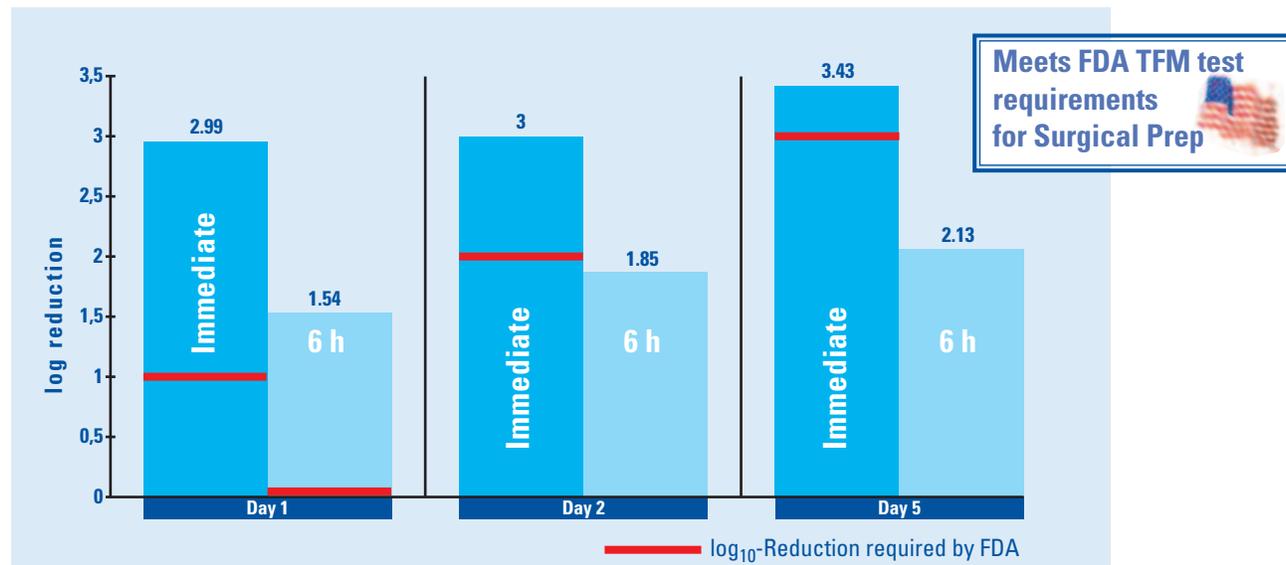
Challenge Microorganism	Reduction in 15 seconds	
	Log ₁₀ *	%
Acinetobacter baumannii (ATCC 19606)	5.62	99.99976
Acinetobacter lwoffii (ATCC 15309)	5.69	99.9998
Bacteroides fragilis (ATCC 25285)	6.02	99.9999
Burkholderia cepacia (ATCC 25416)	5.65	99.99978
Candida albicans (ATCC 10231)	5.97	99.99989
Clostridium 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

**Vegetative state

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 day 1.



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

WHO recommends alcohol-based products

The 2009 WHO Guideline (5) states that the antimicrobial efficacy of alcohol-based formulations is superior to that of all other currently available methods of preoperative surgical hand preparation (6).

On persistence of alcohols...

- "In addition, the initial reduction of the resident skin flora is so rapid and effective that bacterial regrowth to baseline on the gloved hand takes more than six hours. This makes the demand for a sustained effect of a product superfluous. For this reason, preference should be given to alcohol-based products." (7)
- "However, the continued presence of a microbicidal chemical to produce a sustained effect may be unnecessary in view of the fact that volatile ingredients such as short-chain aliphatic alcohols (e.g. ethanol, iso-propanol, and n-propanol) appear fully capable of producing the same effect. With their strong antibacterial efficacy, the importance of a sustained effect is questionable, as regrowth of the skin flora

takes several hours even without the explicitly sustained effect of the alcohols." (8)

- "Furthermore, whether a long-term effect (several days), such as recommended in the TFM model, is necessary or not remains a matter for discussion. It is, however, difficult to understand why the efficacy of a scrub is required to increase from the first to the fifth day of permanent use. Ethical considerations would suggest that the first patient on a Monday, when the required immediate bacterial reduction from baseline is only 1 log, should be treated under the same safety precautions as patients operated on the following Friday when, according to the TFM requirement, the log reduction has to be 3.0." (9)

TFM = Tentative Final Monograph (10)

Rapid – but long-lasting

For ongoing effectiveness

Surgical procedures require long lasting effectiveness of hand antiseptics products. To ensure constant safety, a multiplication of organisms naturally found on the skin must be delayed and a passage of resident organisms into the glove juice must be prevented.

Sustained effect

Sterillium® Rub with its high concentration of ethanol (80% by weight) ensures a rapid, but also extensive and thorough effect. It penetrates into the skin layers of the stratum corneum deeply and rapidly. Because of this the number of organisms from the resident flora is reduced as far as possible within 2 minutes. This, again, guarantees a long-lasting effectiveness against the organisms of the resident and temporarily resident hand flora. How?

It has been shown: the higher the concentration of the alcohol, the higher its effectiveness against the resident hand flora. This means that ethanol at a concentration of 80% is far more effective than ethanol at a concentration of 60% (11, 12). Sterillium® Rub's distinctive initial microorganism reduction, from which the skin flora recovers slowly, enables an excellent long-lasting effect. **Sterillium® Rub reduces the microbial count so low that it takes more than 6 hours for the initial amount of organisms to regrow on the skin.***

*in vivo data on file

John M. Boyce* comments:

"I encourage the FDA to eliminate the requirement that alcohol-based hand rubs have a 'persistent' or 'cumulative' activity. [...] Given the increasing concern over the possible emergence of antiseptic-resistant bacteria, it seems unwise to require that all alcohol-based hand-rubs contain an additional antiseptic in order to demonstrate a 'persistent' or 'cumulative' effect.

[...] Furthermore, since these products are used many times during the day for the disinfection of the hands, there is no reason for them being more effective at the end of the work day than at the beginning of a work shift." (13)

* John M. Boyce, MD, Professor of Medicine, Chief of Section of Infectious Diseases, Hospital of Saint Raphael, New Haven, CT, USA, and author of Hand Hygiene Guideline for Healthcare Settings, published by the CDC.

**Sterillium® Rub provides
a rapid, thorough and long-lasting
hand antiseptic effectiveness.**

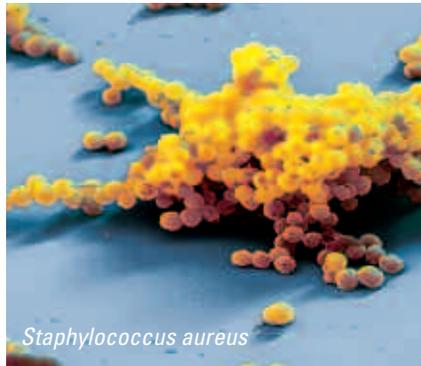




Comparison of efficacy

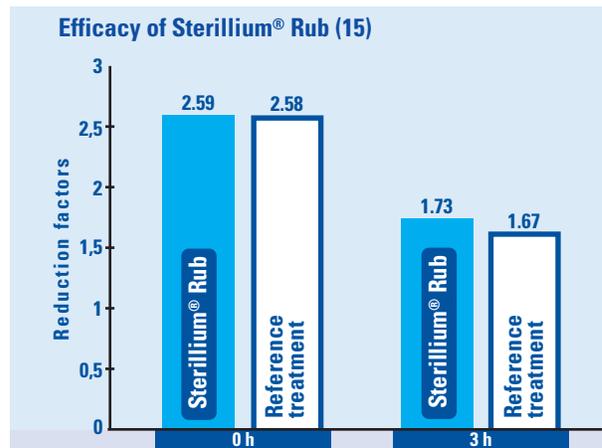
Sterillium® Rub compared to conventional waterless products

All test results show how effective Sterillium® Rub is, but what does the comparison to a surgical antiseptic product also available on the market look like?



Efficacy for surgical hand disinfection

Sterillium meets all requirements for a surgical hand rub and is very potent, with both immediate and sustained efficacy. The high concentration of ethanol (80% w/w) was found to be efficient on resident hand flora. The EN 12791 test method is particularly suitable for the differentiation and comparison of various preparations based on different active agents (14). Knowing this, 3M™ Avagard™ was tested side by side with Sterillium® Rub. Based on published data of a controlled cross-over trial according to EN 12791, Sterillium® Rub is as effective (immediate and sustained effect) as the reference alcohol and meets the requirements for a surgical hand rub (15).



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

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	
3M™ Avagard™	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 a reference alcohol (60% n-propanol)

With Sterillium® Rub you have an effective hand antiseptic with maximum safety and comfort at hand.

Chlorhexidine-free

Doing without chlorhexidine – on purpose.

Formulation science has evolved. It is now possible to deliver persistent activity as defined by the FDA TFM without CHG. Why should you consider avoiding CHG for hand antisepsis?

CHG – a potential for skin irritations

The possible emergence of antiseptic-resistant bacteria is not the only side-effect of CHG as an additional antiseptic agent. As we know, skin irritations by hand antiseptic agents constitute a barrier to appropriate compliance in hospitals (1).

“Antiseptics such as chlorhexidine gluconate have an increased propensity to cause irritant contact dermatitis when used frequently,” says John M. Boyce (13). This is not to imply it is not an excellent patient prep (single use) option.

Furthermore, allergic reactions with CHG have been reported. Allergic contact dermatitis associated with alcohol-based hand rubs is uncommon (16).

These observations raise doubts as to the justification of chlorhexidine gluconate as an additional antiseptic agent in alcohol-based products for hand antisepsis, where it is so frequently applied.

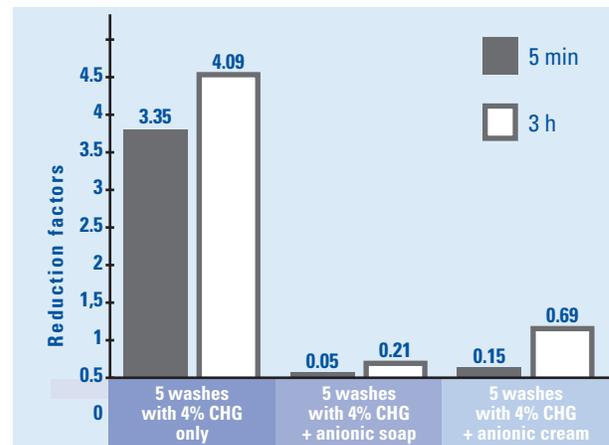
Resistances to CHG

“There is a considerable concern that some antiseptics may promote emergence of bacteria with resistance mechanisms similar to those responsible for antibiotic resistance,” says John M. Boyce (13).

Repeated exposure of bacteria to chlorhexidine gluconate may lead to adaptation and enhancement of the resistance towards it (17). In 1982 this was already suspected by scientists at the Tokyo University (18).

Gram-negative bacteria, such as *Escherichia coli*, *Pseudomonas mirabilis*, *Providencia stuartii*, *Pseudomonas aeruginosa*, *Pseudomonas cepacia* and *Serratia marcescens*, have frequently been reported to be resistant to CHG. *Candida albicans* was found to have a resistance rate of 10.5%. In hospitals it was generally observed, that a higher exposure of bacteria to CHG involved a higher rate of resistance. Such resistances to CHG might even result in nosocomial infections. Occasional outbreaks of nosocomial infections have been traced to contaminated solutions of CHG.

Especially since a resistance to chlorhexidine gluconate is endemic in gram-negative bacteria, the use of CHG-based hand antiseptics may lead to an increase of nosocomial infections by the CHG-resistant species (17).



Mean \log_{10} reduction of *Serratia marcescens* applied after 5 washes with 4% CHG followed by no treatment, anionic soap or anionic cream after wash 5 (19).

CHG’s compatibility with soaps

The CDC guideline for surgical hand antisepsis with an alcohol-based antiseptic indicates: “Before applying the alcohol solution, prewash hands and forearms with a non-antimicrobial soap and dry hands and forearms completely.” (20)

But did you know, that the combination of positively charged chlorhexidine gluconate and negatively charged compounds, like sulfates – being an ingredient of non-antimicrobial soaps – form salts of low solubility? Even worse, it was discovered and published in 1990 that anionic soap or anionic cream reduces or even neutralizes the germicidal effect of CHG in handwashes for surgical antisepsis (19).

What does this mean to you? It means that the persistent effect of CHG is eliminated when non-compatible soaps/detergents are used on the skin.

Sterillium® Rub Dispensers



The Sterillium® Rub dispensers are unique, flexible and easy to use. The wall bracket supports all versions (auto & foot & manually operated) of the dispenser. It can either be mounted with screws or double-sided tape.

LXT10AUTO Touchless Dispenser - 1/ea

Touch-free hand hygiene supports compliance

For ease of use and product acceptance, you can rely on the LXT10AUTO dispenser.

The battery-operated IR sensor activates the pump and a precise volume of 1.2 mL of Sterillium® Rub is dispensed into your hand. The technology is highly efficient.

The LXT10AUTO Touchless Dispenser requires 4 "D"-size batteries (not included).

- State-of-the-art technology
- Touch free activation
- Highly efficient – ensures a long life time
- User friendly
- Easy battery exchange
- Battery life indicator
- Adjustable sensor



LXF10FOOT Foot-Operated Dispenser - 1/ea

The easy to clean foot pedal is made of solid plastic with non-skid rubber feet. It too dispenses a metered dose of 1.2 mL per activation.

Cable length: 6.58 feet.

- User friendly
- Enduring functionality



Sterillium® Rub Dispensers

Ordering Information

Item Number	Description	Size	Packaging
MSC097060	Sterillium® Rub Bottle	1000 mL (33.8 fl. oz.)	8/case
MSC097059	Sterillium® Rub Spray Bottle	50 mL (1.69 fl. oz.)	50/case
LXT10AUTO	Touchless Dispenser		1/case
LXF10FOOT	Foot Operated Dispenser		1/case
STRLMSINK66	Stainless Steel Sink Bracket	66° angle	4/case
STRLMSINK90	Stainless Steel Sink Bracket	90° angle	4/case
STRLMDRIPLONG	Drip Tray		12/case
MSC9204	Nail Picks	150 each/bottle	6/case



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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 if 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.

Sterillium® brand – U.S. Product Range

Sterillium® Rub

- Surgical Hand Antiseptic
- Visit the www.medline.com/sterilliumrub to learn more

Sterillium® Comfort Gel™

- Healthcare Personnel Hand Antiseptic
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