STERIS

Disinfectants and Sporicides for 503A Sterile Compounding Facilities: Selection and Use

Disinfectants and sporicides perform critical functions by killing a broad spectrum of common bacteria and fungi and destroying the toughest environmental contaminants such as spore-formers. Product selection and development of an effective disinfection routine is essential for maintaining your sterile compounding facility.

The table below, taken from USP <797> (2019 proposed), is a useful aid in selecting products and developing effective routines for best results.

		Recommended STERIS Cleaning Chemistry to Utilize		
		MICROBIAL EFFICACY →		
Site to Be Cleaned/Disinfected	**Required *Minimum* Frequency of Cleaning/Disinfection**	**Septihol™ st[3] 70% IPA**	**Vesta-Syde™ SQ 64 RTU[2]**	**Spor-Klenz™ RTU[4]**
Equipment and all interior surfaces of the Primary Engineering Control (PEC)[1]	Daily and when surface contamination is known or suspected		✓	
Equipment and all interior surfaces of the Primary Engineering Control (PEC)[1]	Monthly		✓	✓
Horizontal work surface of the PEC(s)	At least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted and the work surface of the PEC must be disinfected immediately after compounding.	✓		
Removable work surface of the PEC	Daily		✓	
Surfaces and the area underneath the work tray	Monthly		✓	✓
Pass-through(s)	Daily		✓	
Pass-through(s)	Monthly		✓	✓
Work surfaces(s) outside of the PEC	Daily		✓	
Work surfaces(s) outside of the PEC	Monthly		✓	✓
Floors	Daily		✓	
Floors	Monthly		✓	✓
Walls, doors, and door frames	Monthly		✓	✓
Ceilings	Monthly		✓	✓
Storage shelving and bins	Monthly		✓	✓
Equipment outside of the PEC(s)	Monthly		✓	✓
Surfaces of sinks	Daily		✓	
Surfaces of sinks	Monthly		✓	✓

[1] After the application of a one-step disinfectant cleaner or application of a one-step sporicidal agent in the PEC, apply sterile 70% IPA to remove any residue left behind.
[2] Many disinfectants registered by the EPA are one-step cleaning and disinfecting agents, which means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a separate cleaning step. STERIS offers other one-step cleaning and disinfectant agents such as LpH™ III, Vesphene™ III and Vesta-Syde SQ 128 Ready to Use (RTU) Disinfectants.
[3] USP <797> only requires that 70% IPA be sterile. One-step disinfecting agents and sporicidal agents need not be sterile, but STERIS does offer sterile products if needed. Stepihol st Alcohol Solution provides biocidal and fungicidal activity for an additional level of microbial control during disinfection and rinsing.
[4] Spor-Klenz™ RTU Sterilant requires the use of a cleaning step first and must be used in conjunction with the Vesta-Syde™ SQ 64 RTU Disinfectant for the listed cleaning tasks.

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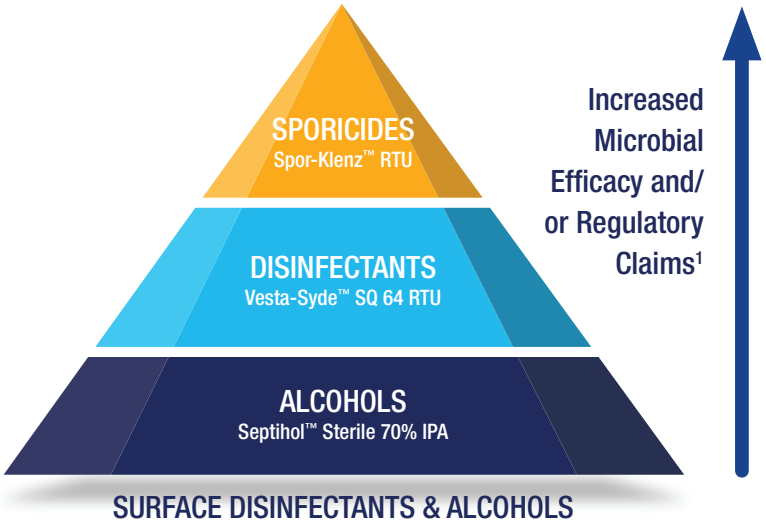
Our dedicated team can help customize your cleaning and disinfection program to meet your unique needs.



[1] Products that fall into the categories at the bottom of the pyramid are most frequently used and are generally not sporicidal. Progression up the pyramid indicates stronger performance overall and a broader spectrum of claims.

STERIS offers a selection of high-quality disinfectants and sporicides to help maintain microbial control of your sterile compounding facility. Our Spor-Klenz™ family of Ready to Use (RTU) Sterilants offer fast, broad spectrum efficacy, superior material compatibility and low residues, ideal for use on a monthly or more frequent basis in accordance with USP <797> (2019). For daily use on hard, non-porous surfaces, STERIS Vesta-Syde™ SQ RTU products are phosphate-free, EPA-registered one-step quaternary ammonium disinfectants.

For more information, or for help selecting the best product to suit your facility's unique microbial control needs, contact your STERIS representative or visit sterislifesciences.com.