

# The Impacts of Disinfectant Residue

## Frequently Asked Questions



### What's the science behind disinfectant residue and how does it influence cleanroom contamination control?

Disinfectant formulations designed to effectively clean and kill microorganisms all leave some residue from active ingredients and surfactants. Surfactants remove soils, and active ingredients eliminate microorganisms. **Our testing shows that with proper application procedures and techniques, residues from STERIS disinfectants do not conceal microorganisms, do not accumulate to uncontrollable levels, do not reduce the efficacy of STERIS liquid sporicides and do not compromise contamination control.** To keep your cleanroom well-maintained, perform periodic rinsing. While rinsing after every application is unnecessary, periodic rinsing efficiently removes residues and maintains effective microbial control.

### What do current industry guidelines say about disinfectant residue removal?

Current guidelines emphasize a risk-based approach. For non-product contact surfaces, there is no prescriptive regulatory standard for residue removal. The industry standard is “visually clean” rather than applying analytical limits. Overly rigorous testing on these surfaces can introduce unnecessary complexity and risk without improving product quality or patient safety.

### How does EU GMP Annex 1 specifically address disinfectant residues in cleanrooms?

EU GMP Annex 1 states that disinfectant residues should be removed, but it does not specify frequency, method or limits. The primary emphasis of the disinfection section of Annex 1 is on effectiveness of disinfectants, not residue control. Section 4.33 mentions residue only once, while stressing efficacy four times.

### How should you handle disinfectant residues on non-product contact surfaces like floors?

For floors and other non-product contact surfaces like walls and ceilings, aim for visual cleanliness. Implement a period rinsing program (e.g., monthly) using proper techniques.

- Use a two- or three-bucket system with Water for Injection for rinsing
- Wipe or mop with unidirectional, overlapping strokes to prevent spreading residue

### What should you look for in a disinfectant to ensure cleanroom compliance and performance?

When selecting a disinfectant for cleanroom use, focus on these key factors:

- **Efficacy:** Select a disinfectant that effectively kills microorganisms and maintains microbial control
  - **Compatibility:** Confirm that the disinfectant does not cause damage to cleanroom surfaces, application tools and other materials
  - **Efficiency:** Use registered one-step cleaner/disinfectants to reduce complexity and meet the Annex 1 requirement for cleaning prior to disinfection
  - **Simplicity:** Select a product that applies easily and ergonomically to walls, floors and ceilings
- Important Note:** Avoid selecting products solely for low residue claims, as this can compromise efficacy and increase operational complexity.

### What proven strategies can help you manage disinfectant residue in your cleanroom?

Disinfectant residues are a normal result of an effective formulation and are typically water soluble. Rinse periodically with Water for Injection, such as monthly or whenever residues are visible, to remove them quickly and effectively. For smaller surfaces like stainless steel or glass inside a biosafety cabinet, use alcohol wipes for a simple and efficient approach.