



## CLEANING AND DISINFECTION IN USP REGULATED ENVIRONMENTS

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The United States Pharmacopeia (USP) Compounding Compendium – 2017 provides guidance on compounding (mixing) substances in pharmacies and the level of cleaning/disinfection which must occur. This document discusses cleaning and disinfection outlined in relevant USP guidelines and offers comments on the appropriateness of using Diversey products.

**USP 795 Pharmaceutical Compounding – Non-sterile Preparations** does not provide specific guidance on materials or chemistries to be used for cleaning and disinfection, this document recommends that work areas just need to be clean and sanitized.

*Diversey Products (dilutable products, ready to use solutions and wipes, TASKI®SUM mops) would meet the language of USP 795.*

**USP 797 – Pharmaceutical Compounding – Sterile Preparations** has prescriptive language on cleaning and disinfecting areas where sterile compounding occurs. The recommended disinfectant characteristics are discussed below, see **USP 1072**.

The Primary Engineering Control (PEC) is the device or room that provides an ISO Class 5 environment (particle counts of less than 100 / ft<sup>3</sup>) for the exposure of critical sites when preparing Compounded Sterile Preparations (CSPs). Such devices include, but may not be limited to laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

USP 797 states the PEC must be cleaned and disinfected:

- at the beginning of each shift,
- before each batch,
- not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring,
- after spills, and
- when surface contamination is known or suspected.

Counters, floors and easily cleaned work surfaces outside of the Class 5 PEC (Class 7 and 8 areas) must be cleaned and disinfected daily. Walls, ceilings and storage shelving must be cleaned and disinfected monthly.



### Diversey Cleaning Equipment

USP 797 language states that all cleaning materials used for disinfection, such as wipers, sponges, and mops, shall be non-shedding, preferably composed of synthetic microfibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. For spills within the compounding area, sterile water and low-shedding wipes should be used.

There is no definition, or standard offered, for 'low-' or 'non-shedding' in the document.

USP 797 states floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation.

USP 1072 (see below) recommends that disinfectants are diluted with Sterile Purified water, or filter sterilized before use. The language does not state that the disinfectant must be used 'sterile', just that either sterile purified water is used to dilute the product or the prepared product is filter-sterilized. The chapter also indicates it is 'prudent to augment the daily use of a bactericidal disinfectant with weekly (or monthly) use of a sporicidal agent.

*Diversey disinfectant wipes, and TASKI@SUM equipment is NOT considered non-shedding or lint free, our wipes are classified as low-linting. Our disinfectant products are not packaged aseptically nor can they be considered sterile.*

**USP 1072 – Disinfectants and Antiseptics** provides language on issues with appropriate cleaners, disinfectants, antiseptics and equipment used. The language can be contradictory in this chapter, as fungal and bacterial spores are used interchangeably or considered equal in terms of difficulty in killing. Language on rotation of disinfectants is also misleading, dated in concept, and without literature support. There is also language on testing commonly isolated organisms (found through routine culturing of the sterile compounding area) for their susceptibility to disinfectants. With this type of surface culture, pharmacies would be aware of what organisms they are seeing enter their sterile compounding area, and would then be able to select for a disinfectant to handle the organisms. USP 1072 needs to be updated with current literature.

### Conclusion

- Each pharmacy is to have a standard operating procedure that is acceptable to the facility (and any inspection agency) on cleaning and disinfection of any area, including within pharmacies.
- Diversey products would be acceptable to use in non-sterile preparation areas of pharmacies, as outlined in **USP 795**.
- Diversey products do not meet the requirements of **USP 797** for sterile compounding areas, but could be acceptable for Class 7 and Class 8 (non-sterile) areas adjacent to the Class 5 sterile compounding areas.
- A facility may be comfortable with using our products, and we have a responsibility to ensure customers understand the limitations of our products in respect to the above documents, to ensure they have the best possible results.



**NON-STERILE COMPOUNDING - CLASS 7, 8 CLEAN ROOMS – DIVERSEY PRODUCTS:**

Product	Oxivir® 1 RTU / Wipes	Oxivir® Tb RTU / Wipes	Oxivir® Five 16	Alpha® HP Multisurface Disinfectant Cleaner	Avert™ Sporicidal Disinfectant Cleaner/Wipes	Virex® II 256	Virex® Tb	Virex® Plus	Expose® II 256	MoonBeam®3 UV Disinfection
Contact Time (Min)	1	1	5	5	1	5	3	3	10	3
										

If there are any questions about this assessment or any Diversey products, please contact Diversey Customer Technical Support at 1-800-558-2332, option 5.