

CriticalPoint Pearls of Knowledge

Cosmetics and the Compounding Environment

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Introduction

If you are a designated person (DP) responsible for staff garbing compliance, you likely have had intense conversations regarding cosmetics. USP <797> states that personnel are to remove all cosmetics because they shed flakes and particles. Unfortunately, the chapter does not define what is considered a cosmetic.

The [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product.

The [Modernization of Cosmetics Regulation Act of 2022](#) (MoCRA) amended the FD&C Act to include "cosmetic product" which is defined as "a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product" [FD&C Act, sec. 361]. This new term applies to these amendments of the FD&C Act.¹

This Pearl bridges the gap between what the FDA defines as a cosmetic and what we need to consider to be a cosmetic, as it relates to sterile compounding, by addressing the common types of cosmetics and CriticalPoint's best practice recommendations.

Setting expectations

There are many different types of cosmetics available. Compounding facilities are tasked with addressing the various kinds of cosmetics and making it clear to all who enter compounding environments why certain cosmetics are prohibited. This is best accomplished by including cosmetic-related expectations in the facility's standard operating procedures (SOPs). CriticalPoint also recommends the designated person, pharmacy manager, and human resources department work together to create a job description for compounding personnel that includes:

- a description of the compounding duties
- a list of physical demands
- how to report to work
- expected operator conduct, which includes following facility SOPs



This sets the expectation for new hires of what is required of them to work in the compounding environment. If there are ever issues with personnel complying, refer them back to the job description.



Nails

USP <797> states “keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails, and extenders) must not be worn.”² CriticalPoint likes to add more detail to make it crystal clear what is expected, and each facility should do the same.

The following nail products are **not** allowed:

- gel nails
- glue-on nails
- nail polish, including clear
- nail extensions
- powder nails



Nails must be natural and neatly trimmed. If, while holding your hands in front of you with palms facing toward you, you can see your nails, then they are too long.

When compounding personnel understand the reasoning behind the rules put in place, they have the rationale and data needed to support the facility’s decision to implement specific procedures and standards. Personnel armed with this information will be able to pass it along to future employees, encouraging a knowledgeable and compliant workforce.

There are several reasons why short, neatly trimmed, natural nails are preferred.

- Long nails are more likely to puncture gloves.
- Nail polish and extensions can cause flaking and chipping and are also a concern for microorganisms.
- Most of the microbial growth is along the proximal 1 mm of nail adjacent to the subungual skin.³
- Patient deaths have been associated with nurses’ poor hand hygiene practices with long and artificial fingernails.⁴

Makeup

We still see compounding facilities struggle with compounding personnel challenging the wording in USP <797> to find loopholes that will allow them to wear makeup in the compounding environment. USP <797> states, “remove all cosmetics because they shed flakes and particles.”² No makeup of any kind is allowed in the compounding environments. This includes:

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| • blush | • eyelash extensions that an esthetician applies | • glue-on or magnetic eyelash strips | • lip gloss |
| • eyebrow pencil | • foundation | • highlighter/bronzer | • lip liner/lipstick |
| • eye shadow | | | • mascara |

Some of you may not be aware that makeup is not sterile when first opened. There is a minimal acceptable number of colony-forming units (CFUs) allowed to be present in packaged makeup from the factory. That means we are adding microorganisms to our faces when applying makeup. Once opened, makeup quickly becomes contaminated with even more microorganisms. We also must consider the number of particles we shed when using makeup. The application of makeup increases the number of particles shed; think of the makeup in powder form that is applied to the face. Those particles are



visible and not appropriate for our compounding environments, especially after learning that they are contaminated with microorganisms.

There is no definitive evidence that an eyelash extension applied by an esthetician will shed at a faster rate than a natural eyelash, but we still would not allow them in our compounding environments.

Wearing them may be a regulatory risk. If your facility decides to allow eyelash extensions, we encourage the addition of goggles to the garbing procedure.

Moisturizers

When it comes to moisturizers, the FDA views this as a cosmetic, but CriticalPoint encourages applying unscented skin moisturizer that does not contain a tint to the face and forearms. Do not apply skin moisturizer right before performing hand hygiene, as this does not allow for effective hand and forearm washing. When leaving the compounding space for break or lunch, apply hand moisturizer to hands and forearms.⁵

Moisturizers prevent dryness and irritation due to repeated hand washing and use of hand rub. They also minimize excessive flaking of dead skin cells.

Hair

Since USP <797> is silent on wigs and hair extensions, many question whether they are allowed in the compounding environment. First, we must identify the various types of hair extensions and wigs. If a compounder has clip-in hair extensions, they must be removed before entering the compounding environment. For sewn-in hair extensions and wigs, treat them as you would a person's regular hair. Wigs must be properly cared for, well fitted so as not to need frequent adjustments, and fully covered by a hair cover when entering the compounding environment.⁶

Compounders are not allowed to wear hair clips, barrettes, bands, hair jewelry, etc., even if located under the hair cover. These can interfere with garb and potentially tear the hair cover. Hair accessories typically are not cleaned and can contain microbial contamination. Only hair ties should be allowed.

Hair color and permanent waves can also be an issue for contamination control in the compounding environment. They can increase the amount of hair shedding due to the harsh chemicals found in permanent hair coloring.⁷ It is important to ensure all hair is properly covered by hair covers, which are available in different sizes, or, in some circumstances, a hood. A hood is necessary for people with big or long hair, individuals with religious head coverings, or anyone with a full beard. Temporary hair dye in chalk, powder, or spray form is not allowed in the compounding environments. Since they coat the hair with color,⁸ the dye can shed or flake off the hair.





Compounders should avoid the application of hair products such as hair spray, mousse, gel, and leave-in conditioner. These products tend to have a heavy scent, and most facilities have a scent-free policy. If hair spray or gel is heavily applied, the product can flake from the hair.

Other Cosmetics

You may be wondering about the many other types of cosmetics and how compounding facilities should address them. We developed a [tool listing different cosmetics](#) that includes examples, recommendations, and the rationale. This is a great resource when answering questions as to why a certain cosmetic isn't allowed in the compounding environment.

Summary

USP <797> makes it clear that no makeup or nail products/extensions are allowed in the compounding environment. Since there are gaps, CriticalPoint is providing our specific recommendations and the “whys” for all types of cosmetics. It is the compounding facility's responsibility to implement these requirements and hold its staff to these rules.

Set expectations in advance by including them in the job description so there is no room to question established procedures. If personnel compliance is an issue, work with your human resources department on a compliance program. Compounding personnel must be held accountable for their actions. Establishing organizational procedures and keeping your compounding personnel accountable will help ensure high-quality CSPs.

References

- ¹ [Is It a Cosmetic, a Drug, or Both? \(Or Is It Soap?\)](#). U.S. Food and Drug Administration (FDA). September 11, 2024. Accessed 10/3/25.
- ² United States Pharmacopeial Convention, Inc. <797> Pharmaceutical Compounding—Sterile Preparations. 2024.
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- ⁸ Summers J. [The Difference Between Temporary, Permanent, Demi-Permanent and Semi-Permanent Hair Color](#). Matrix. April 17, 2024. Accessed 10/3/25.