

Cosmetics in the Compounding Environment

The FDA defines cosmetics by their intended use, 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.” Among the products included in this definition are **skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any other substance intended for use as a component of a cosmetic product.**¹

Personal hygiene must be respected before entering a compounding environment. The challenge sterile compounding personnel face when following USP 797 is the reference to cosmetics with no granular detail provided. One could assume it is the same as the FDA definition. That would likely make requirements stricter than the USP Compounding Expert Committee intended. CriticalPoint created this tool to eliminate confusion and help sterile compounding facilities identify potential contamination risks from cosmetics and other related products in the compounding environment.

Item	Examples	CriticalPoint Recommendation	Rationale
Moisturizer	<ul style="list-style-type: none"> • Face cream • Hand cream • Lip balm 	<ul style="list-style-type: none"> • Even though the FDA views moisturizer as a cosmetic, CriticalPoint encourages applying skin moisturizer that does not contain any tint or scent (see below) on 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.² 	<ul style="list-style-type: none"> • Moisturizers prevent dryness and irritation due to repeated hand washing and use of hand rub. • They also minimize excessive flaking of dead skin cells.
Scents	<ul style="list-style-type: none"> • Body spray • Cologne • Perfume • Scented lotion 	<ul style="list-style-type: none"> • Sterile compounding personnel should refrain from applying scented lotion, perfume, cologne, or body spray to their bodies and/or clothing. 	<ul style="list-style-type: none"> • Most healthcare facilities are scent-free environments. • The issue with body spray, perfume, or cologne is it can be irritating to others; but it is also a particle concern in cleanroom suites. This would be especially concerning in a GMP facility.



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Item	Examples	CriticalPoint Recommendation	Rationale
Nails and nail polish	<ul style="list-style-type: none"> • Gel nails • Glue-on nails • Long nails • Nail polish (including clear) • Nail extensions • Powder nails 	<ul style="list-style-type: none"> • There should be no exception to this rule. • Only neatly trimmed, natural nails are allowed for compounding personnel. • If, while holding your hands in front of you with palms facing toward you, you can see your nails, then they are too long. 	<ul style="list-style-type: none"> • Long nails are more likely to puncture gloves. • Nail polish and extensions can cause flaking and chipping and are also a concern for microorganisms. • The majority of microbial growth is along the proximal 1 mm of nail adjacent to the subungual skin.³
Makeup	<ul style="list-style-type: none"> • Blush • Eye shadow • Eyebrow pencil • Foundation • Highlighter • Lip gloss • Lip liner • Lipstick • Mascara 	<ul style="list-style-type: none"> • Makeup is NOT allowed in the compounding space. This includes the anteroom and the perimeter of the segregated compounding area. • There should be no exceptions for these products. 	<ul style="list-style-type: none"> • The application of makeup increases the number of particles we shed. • 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.
Eyelash extensions	<ul style="list-style-type: none"> • Glue-on or magnetic eyelash strips 	<ul style="list-style-type: none"> • These are considered cosmetics and are not allowed in the compounding environment. 	<ul style="list-style-type: none"> • These types of lashes, which can be applied via glue or magnetic eyeliner, are reusable. • They contain a higher number of microorganisms and must be avoided.
	<ul style="list-style-type: none"> • Eyelash extensions that an esthetician applies 	<ul style="list-style-type: none"> • Eyelash extensions should not be allowed in the compounding environment. • If these are permitted, we encourage the addition of goggles to the garbing procedures. 	<ul style="list-style-type: none"> • There is no definitive evidence showing the lash will shed at a faster rate. • These maybe be a regulatory risk.



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Item	Examples	CriticalPoint Recommendation	Rationale
Hair color and permanent waves	<ul style="list-style-type: none"> • Permanent hair dye • Semi-permanent hair dye • Demi-permanent hair dye • Permanent waves 	<ul style="list-style-type: none"> • Compounders may use these hair dyes and permanent waves. However, if flaking of color occurs, the organization must address the issue. • Ensure all hair is properly covered by a hair cover (available in different sizes) or, in some circumstances, a hood. 	<ul style="list-style-type: none"> • There is not enough evidence to support restricting compounders from this cosmetic. • If frequently applying permanent hair coloring and permanent waves to hair, the harsh chemicals can increase the amount of hair shed.⁴ This is why all hair must be contained inside the hair cover. • A hood is necessary for people with big or long hair, individuals with religious head coverings, or anyone with a full beard.
	<ul style="list-style-type: none"> • Temporary hair dye (powder, chalk, or spray) 	<ul style="list-style-type: none"> • Temporary hair dye cannot be worn into the compounding space. 	<ul style="list-style-type: none"> • Temporary hair dye coats the hair with color. • This dye can shed or flake off the hair.⁵
Wigs and hair accessories	<ul style="list-style-type: none"> • Wigs • Hair extensions that are sewn in 	<ul style="list-style-type: none"> • Those who compound must remove clip-in hair extensions. • Treat wigs and sewn-in hair extensions as you would a person's regular hair. 	<ul style="list-style-type: none"> • This is the same rationale we use for a person's regular hair. • Wigs must be properly cared for, well fitted as to not need frequent adjustments, and fully covered by a hair cover when entering the compounding environment.⁶
	<ul style="list-style-type: none"> • Hair band • Hair clips • Hair jewelry 	<ul style="list-style-type: none"> • Compounders are not allowed to wear hair clips, barrettes, bands, hair jewelry, etc., even if located under the hair cover. • Only hair ties should be allowed. 	<ul style="list-style-type: none"> • They can interfere with garbing by potentially tearing the hair cover. • Hair accessories typically are not cleaned and can contain microbial contamination.
Deodorant	<ul style="list-style-type: none"> • Antiperspirant • Deodorant (spray or roll-on) 	<ul style="list-style-type: none"> • Compounders should apply deodorant and/or antiperspirant. • Select a product that is relatively scent-free. 	<ul style="list-style-type: none"> • CriticalPoint believes perspiration in the compounding area is worse than the application of deodorant or antiperspirant. • Perspiration is wet and can also have a strong odor. • Sweat also contains a high level of microorganisms, as the human armpit has anywhere from 1 to 10 million microorganisms per cm².⁷



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Item	Examples	CriticalPoint Recommendation	Rationale
Microblading and tattoos	<ul style="list-style-type: none"> Any form of indelible skin pigmentation, whether it be permanent makeup, microblading, or tattoos 	<ul style="list-style-type: none"> Tattoos must be fully healed before returning to compounding duties, including no plasma secretions and no scabbing. 	<ul style="list-style-type: none"> USP 797 states that individuals who may have a higher risk of contaminating the CSP and the environment must report these conditions to the DP. It lists “recent tattoos.” Tattoos increase skin shedding, plasma secretions, and scabbing, none of which are allowed in the compounding area.
Waxing and chemical peels	<ul style="list-style-type: none"> Any type of esthetician service that causes the skin to react, such as waxing, threading, laser hair removal, chemical peels, and certain types of facials 	<ul style="list-style-type: none"> Compounders who undergo an esthetic or cosmetic procedure that requires the skin to heal, must refrain from entering the compounding environment until the skin has fully recovered (no more redness, skin shedding/peeling, etc.) 	<ul style="list-style-type: none"> These services cause redness, reaction, and skin irritation, which will cause the skin to accelerate dead skin shedding and peeling.⁸
Other considerations	<ul style="list-style-type: none"> Spray tans 	<ul style="list-style-type: none"> Those with spray tans may enter the compounding area. Spray tans may be a regulatory risk. It is up to the facility to make a decision and document accordingly in SOPs. 	<ul style="list-style-type: none"> There is no definitive evidence showing that spray tans accelerate skin shedding.
	<ul style="list-style-type: none"> Hair products such as hair spray, mousse, gel, leave-in conditioner 	<ul style="list-style-type: none"> Avoid the application of these products when scheduled to work in the compounding environment. 	<ul style="list-style-type: none"> These products most often have a heavy scent; most facilities promote a scent-free policy. If hair spray or gel is heavily applied, the product can flake from the hair.

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4. [Will Hair Dye Cause my Hair to Fall Out?](#) Walk-in Dermatology. January 4, 2021. Retrieved 4/25/23.
5. Summers J. [The Difference Between Temporary, Permanent, Demi-Permanent and Semi-Permanent Hair Color](#). Matrix. April 15, 2019. Retrieved 4/25/23.
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