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Amber Masterbatch for PET Pharmaceutical Packaging Compliant with Regulations upto 2025 & Beyond

29-Apr-21



Avient Corporation, formerly Polyone, has launched a new pelletized amber colorant masterbatch formulated for PET vials, bottles, and other pharmaceutical packaging applications. These unique MEVOPUR™ concentrates use pre-tested ingredients and prescribed manufacturing practices to help customers achieve compliance with pharmaceutical packaging regulations through 2025 and beyond.



Produced under rigorous cGMP and medical manufacturing protocols, the new amber color concentrates are made using only medical-grade ingredients. They are formulated without animal-derived substances and phthalates, and have been pre-tested for compliance with:

- ISO 10993-1 and USP parts <87>, <88> (including class VI)
- European Pharmacopoeia, monograph 3.1.15
- USP <661> and <661.1>
- elemental analysis, as per ICH Q3D

To support customers' Device Master File submission for healthcare materials, Avient has developed and submitted a type III Drug Master File (FDA) for these colorants. They are also approved for food contact in accordance with US FDA and EU norms

The newest amber masterbatches comply not only with the current USP 661 standard, which governs plastic materials used in pharmaceutical packaging, but they have also been tested for compliance to USP regulations that won't become effective until December 2025. As a result, these MEVOPUR masterbatches will "future-proof" pharma packaging and avoid the need for formulation changes in the years to come."

Amber shades are known to be effective in prolonging the shelf life of packaged pharmaceuticals by protecting from degradation caused by UV light. The new MEVOPUR concentrates block wavelengths from 290 – 450 nm, while still providing good transparency. Avient can design these concentrates in a range of amber tones from light to dark, and with more or less red or yellow.

Source: Avient



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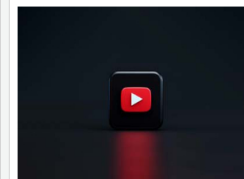
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