Product Bulletin

Stan-Tone™
FDA Silicone Paste colors (FSP)

PolyOne™

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FDA Silicone Paste Colors (FSP)
Stan-Tone™ Colors
To supplement our Stan-Tone™ SP (silicone paste) line, we have developed a palette of 13 silicone paste colors using ingredients regulated under FDA CFR Title 21. Title 21 offers the formulator a good guideline for colorant selection that will meet the requirements for various food- and skin-contact applications, but the burden of securing any required FDA approval of the finished product lies with the manufacturer. Thus, it is very important to test the performance of the colorant in the actual compound being used. These colorants, dispersed in a dimethyl silicone fluid, are formulated at optimum pigment loading, resulting in a paste-like consistency.

Pigments Regulated Under FDA Title 21 CFR
The FDA will list various generic pigments by Chemical Type and/or Colour Index. This list does not guarantee that the pigment will meet the approval requirements; it is the finished product that must gain approval.

Some of the Title 21 listings which include pigments:
- 177.2600 “Rubber articles intended for repeated use”
- 175.300 “Resinous and polymeric coatings”
- 178.3297 “Colorants for polymers”

PolyOne’s Position on Colorants for FDA Applications
PolyOne does not offer “FDA-Approved” colorants; this would imply that we test them in the final manufactured product. Instead, we offer “FDA-Regulated” colorants—their use will result necessarily in an FDA-approved final article in the customer’s application; but it does offer a good starting point to select the best candidate pigment(s) to obtain any necessary FDA approvals for the final manufactured product.

Some of these pigment systems qualify as FDA CFR Title 21 listed ONLY when used in particular elastomers. Check with your technical support resource at PolyOne to confirm your application.

Stan-Tone™ Colorants for Silicone Elastomers
Silicone elastomers are comprised of different types: thermoset gum rubber, one- and two-component RTV systems, and two-part LIM systems. Selection of a colorant must be made to meet the individual requirements of a specific type.

Thermoset Gum Rubber
Typically based on linear fluids or gums with fillers and cured with organic peroxides, thermoset gum rubbers are processed on conventional rubber-processing equipment (2-roll mill, internal mixer, extruder). Thermoset gums are used for a wide variety of applications, typically using conventional fabrication methods such as compression, injection, extrusion and transfer molding. The cure time and temperature, post-cure, and end-use requirements are all factors in selection of colorants.

Thermoset gums typically use the colorants in masterbatch, SMB form for ease of handling, especially for 2-roll open-mill mixing. There are also colorants available in the form of high-viscosity pastes for use in various thermoset applications.

Stan-Tone™ SMB colors are based on a silicone gum binder system. A wide range of high-temperature organic and inorganic pigments are available. Refer to PolyOne’s Stan-Tone™ Silicone Gum Rubber Colors (SMB) brochure for further details. In addition, high-viscosity Stan-Tone™ SP (silicone paste) colors can be utilized in gum formulations.

RTV Compounds
The RTVs are most commonly used for sealants and caulks. There are two types: one-component moisture-cured systems and two-component systems. PolyOne Stan-Tone™ SP (silicone paste) colors offer a standard line of single pigments dispersed in a low-viscosity dimethyl fluid. They can be modified to have varying viscosities from fluid pourable to thick putty. PolyOne is exceptional at providing...
the customer custom-blended multipigment colors. Since the RTVs cure at room temperature, the selection of suitable pigments is much greater, giving the compounder more flexibility.

Refer to PolyOne’s Stan-Tone™ Silicone Paste Colors (SP) brochure for further details.

**LIM System**
The LIM system consists of two pumpable components with a platinum catalyst to speed up the cure. The colorant and other additives are often added via a third mixing head. The colorant must be pumpable and nonsettling. PolyOne offers custom-made colors using a vinyl-terminated reactive silicone especially suited for LIM systems. Pigments containing residual sulfur should be avoided because they can interfere with the platinum catalyst. Many of the applications require nontoxic pigments (examples include facemasks, baby bottle nipples, medical prostheses).

**General Information**
PolyOne surpasses at finding the best solution to meet the performance requirements with the most economical pigment system.

PolyOne has a minimum order quantity of 5 gallons (40-65 pounds).

PolyOne colorants can be selected to meet any or all of the following characteristics:

- Indoor or outdoor lightfastness
- Heat stability – time and temperature
- Toxicity – toy, medical, food, cosmetics, etc.
- Ease of dispersion
- Optimum economics
- Heavy metal replacement
- Chemical resistance

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**Table:**

<table>
<thead>
<tr>
<th>Stan-Tone Code</th>
<th>Pigment Type</th>
<th>Approx. % Pigment</th>
<th>Specific Gravity</th>
<th>Color Index</th>
<th>Heat Stability</th>
<th>Lightfastness</th>
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<tbody>
<tr>
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<td>10FSP03</td>
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<tr>
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**KEY**

- RS = Red Shade
- YS = Yellow Shade
- VYS = Very Yellow Shade
- BS = Blue Shade
- VBS = Very Blue Shade
- GS = Green Shade
- (a) = Furnace Black Might Interfere with Peroxide Cure Systems

**Lightfastness**

- I = Indoor Only
- I/O = Indoor or Outdoor
- Mass = Outdoor Masstone Application Only
- C = Some Caution Advised

**Heat Stability**

- 1 = Above 400°F
- 2 = 350°F - 400°F
- 3 = Below 350°F
- C = Some Caution Advised
Product choices often vary by region due to differences in regulatory and agency requirements, availability and other key factors. Please contact your nearest sales office for assistance in choosing the right solution for your locale.