



» PRODUCT BULLETIN

MEVOPUR™ LQ

Liquid Color & Additive Concentrates for Silicone Elastomers

Silicones elastomers are materials of choice in a wide range of medical applications because of the combination of unique physical properties such as strength, durability, and flexibility combined with one of the most tested polymers in terms of biocompatibility and hypo-allergenic properties.

The MEVOPUR™ LQ advanced range of liquid color & additive concentrates utilize the specific liquid carrier system designed for high compatibility with silicone elastomers. The color-stable, highly compatible ingredients including pigment, carrier and additives used in these concentrates are evaluated to industry standards and help reduce the risk of interaction with the body or the drug.

We offer a customized dosing and handling system that can be integrated with existing processing equipment. A wide range of opaque and translucent colors is available, as well as the option to work with us for any custom color requirements.

KEY CHARACTERISTICS

- Wide range of opaque and translucent colors including standard colors (see examples in color chart). Customized color solutions are available on request
- Production under ISO 13485 / GMP quality system with change control management
- Fingerprinting of raw materials and routine batch testing
- Extractability evaluated in hexane, isopropanol, and water according to ISO 10993 part 18

REGULATORY SUPPORT

- Raw materials are pre-tested to biologically-evaluated raw materials using ISO 10993-1 and USP chapters <87>, <88> Class VI
- DMF/MAF documentation filed with the FDA for all standard colors

APPLICATIONS

MEVOPUR LQ formulations can be applied in demanding applications including:

- Medical devices such as catheter tubing & connectors, syringe tips, and needleless connectors
- Skin contact devices such as wearables or soft-touch surfaces of medical devices



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Avient products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices categorized by either the United States Food and Drug Administration (FDA) or the International Standards Organization (ISO) as an “implant” device; or “Permanent” as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices for “Long Term” use as defined in EU Directive 93/42/EEC as amended.

Without limiting the generality of this statement, Avient products shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) “plastic” (cosmetic or reconstructive) surgery use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, and with all applicable laws and regulations.