

TDS KMPSI-65-PL

DESCRIPTION:

KMPSI-65-PL is a two-part, addition-cure, platinum catalyzed silicone elastomer designed for use in processes where high strength molded parts or extruded profiles are desired. It is formulated for rapid cure in transfer and compression molds and in short-dwell vulcanizing ovens for extrusion processes. KMPSI-65-PL is formulated to meet the requirements of USP class VI requirements and can be used in short term (under 30 days) implant material.

APPLICATIONS:

- Molded or extruded medical parts for <30 day implantation
- Healthcare applications: stoppers, plungers, seals, needle entry ports, tubing

FEATURES:

- No volatile cure by-products
- Optional post cure
- Non-tack y surface
- Non-blooming
- No peroxide residue

<u>Product Properties</u>	<u>Test Method</u>	<u>Value</u>
Mixed A:B 1:1 ratio	CTM	
- Appearance		Clear, translucent solid
- Specific Gravity	TP 013	1.18
- Pot Life, 23°C hours	NM 128	8

Cured 10 minutes, 120°C	ASTM	
- Hardness, Shore A	D 2240	65
- Tensile Strength, psi (N/mm ²)	D 412	1,480 (10.2)
- Elongation, %	D 412	740
- Tear Strength, ppi (N/mm)	D 624, Die B	240 (42)
- Tension Set, %	D 412	3

Please note: The typical properties listed in this bulletin are not intended for use in preparing specifications for any particular application of MEREFSA, Please contact our Technical Service Department for assistance in writing specifications.

INSTRUCTIONS FOR USE:

Parts A and B components of KMPSI-65-PL are designed to be mixed in equal parts by weight or volume using standard rubber processing techniques such as two roll milling. For optimum results, freshen both parts separately on the two roll mill before mixing them. Do not allow the material temperature to exceed 30°C during the milling. The mixed material should be used within two hours to prevent structuring and premature crosslinking. Molding is typically 10 minutes at 120°C or 3 minutes at 165°C.

CURING:

Curing can be achieved in 10 minutes at 120°C. Post curing for one hour at 165°C is recommended to stabilize physical properties. For extrusion applications, cure for 3 seconds at 593°C.

POT LIFE:

The mixture of Parts A and B components of KMPSI-65-PL will remain stable for at least 6 hours at 23°C. Working time can be further extended by storing the mixed material in a freezer.

CLEANING:

Care must be taken to work in a clean area with clean equipment, as traces of foreign materials can poison the catalyst, and inhibit the cure.

PRECAUTIONS:

Accurate measuring and complete mixing are essential in obtaining consistent results.

Contamination by trace amounts of compounds containing sulfur, amines and organometallic salts can result in unreliable cure of the material. **Never handle this material with late gloves.** Organic rubbers and tin catalyzed silicones often contain compound which can interfere with the cure of this material and should be avoided.

LIMITATIONS:

Silicone products are used for certain food contact, healthcare, medical and pharmaceutical applications. Merefsa supports the sales of these products to customers involved in manufacturing and assembling approved medical devices for less than 29 day implantation. The purchaser has the sole responsibility to select a particular Merefsa product and determine its application suitability. The purchaser also has the sole responsibility to comply with all applicable statutory, regulatory and industry requirements and standards for compatibility, extractability, testing, safety, efficacy and labeling.

STORAGE AND SHELF LIFE:

KMPSI-65-PL when stored in its original unopened packaging, at a temperature of 24°C (77°F), may be stored for 12 months from the date of manufacture. Beyond this date, Merefsa no longer guarantees that the product meets the sales specifications.

SAFETY:

Please read the container labels for KMPSI-65-PL or consult the Material Safety Data Sheet (MSDS) before handling for safe use, physical and health hazard information. The MSDS is not included with the product packaging, but can be obtained by contacting Merefsa at 0034 93 337 20 81 or consult your Merefsa representative.

PACKAGING:

KMPSI-65-PL is available in 22,6 kg kits.