

SILBIONE® BIOMEDICAL HCRA M500 SERIES

Implantable Grade High Consistency Rubber

Technical Data Sheet n° – October
2017

Description

SILBIONE® BIOMEDICAL HIGH CONSISTENCY RUBBERS (HCRs) are two-component platinum-catalyzed silicone elastomers designed for extruding or injection molding medical parts, including long-term implant (30 days or more) applications.

Available in a full range of hardnesses from 20 to 80 durometer – Shore A, Elkem Silicones' **SILBIONE® BIOMEDICAL HCRs** offer the distinctive advantages of easy processing and easy release combined with high performance physical properties.

Advantages

- Easy to mill and extrude
- Rapid cure at elevated temperatures.
- Good clarity
- Can be post-cured, but post-cure is not necessary to achieve desired physical properties.
- Manufactured and packaged in ISO certified controlled environments

Processing

SILBIONE® BIOMEDICAL HCRs are supplied as kit-matched products. Parts A and B components are designed to be mixed with standard mill, extruder, or injection molding processing equipment and techniques.

Cure:

Cure is initiated once the two-part part A and part B components are mixed and can be accelerated by heating the mixed elastomer. Cure is dependent upon temperature and part or profile size.

Special care must be taken to assure clean mixers, mills, dies, molds and a clean work area with no organic rubbers used on the same processing equipment.

Caution: Traces of foreign materials can poison the catalyst and inhibit the cure. All metering and mixing equipment should be thoroughly cleaned. Polymer systems, which contain traces of amines, sulfur, nitrogen oxide, organotin compounds and carbon monoxide can interfere with the cure of this product and should be avoided.

Note: Kit matching, accurate measuring and complete mixing are essential factors in obtaining consistent results.

SILBIONE® BIOMEDICAL HCRA M500 SERIES

TYPICAL PROPERTIES

AS SUPPLIED

<i>Typical properties</i>	ASTM	HCRA M520	HCRA M530	HCRA M540	HCRA M550	HCRA M560	HCRA M565	HCRA M570	HCRA M580
Appearance	TP 038	Clear	Clear	Clear	Clear	Clear	Clear	Clear	Clear
Mix Ratio	-	1:1	1:1	1:1	1:1	1:1	1:1	1:1	1:1
Specific Gravity	TP 013	1.11	1.12	1.13	1.14	1.15	1.17	1.18	1.2

PRESS CURE, 15 minutes, 177°C (350°F), Cold Mold

<i>Typical properties</i>	ASTM	HCRA M520	HCRA M530	HCRA M540	HCRA M550	HCRA M560	HCRA M565	HCRA M570	HCRA M580
Hardness, Shore A	D2240	20	30	40	50	60	65	70	80
Tensile strength, Psi	D412	1250	1700	1650	1650	1550	1500	1450	1250
Elongation, %	D412	1000	1000	975	950	775	725	700	650
Tear strength, Ppi	D624 Die B	225	250	250	300	265	250	235	225
Work Life, hr	D412	2	3	4	4	4	4	4	4

CURE KINETICS, MDR, 5 minutes, 115°C (240°F)

<i>Typical properties</i>	ASTM	HCRA M520	HCRA M530	HCRA M540	HCRA M550	HCRA M560	HCRA M565	HCRA M570	HCRA M580
t ₂ , minutes	D5289	0.2	0.15	0.2	0.2	0.15	0.15	0.15	0.15
t ₉₀ , minutes	D5289	0.5	0.5	0.5	0.5	0.3	0.3	0.3	0.3
Prate, llb/min	D5289	30	40	45	55	65	80	85	120

Please note: The typical properties listed in this bulletin are not intended for use in preparing specifications for any particular application of SILBIONE silicone materials.

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Regulation

Biocompatibility Testing

Designed specifically for long-term implant applications, **SILBIONE® BIOMEDICAL** brand materials have been tested according to, or are substantially equivalent to, materials that have been tested according to ISO 10993/USP Class VI for:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation (ISO 10993)
- Intracutaneous Toxicity (USP)
- Systemic Toxicity
- Mutagenicity
- Hemolysis
- Pyrogenicity (USP)
- 12-Week Implant

FDA Master Files

Master Files (MAFs) in support of **SILBIONE® BIOMEDICAL** brand products are on file with the U.S.FDA. Customers interested in referencing these files must contact an Elkem Silicones representative.

Limitation

The purchaser has the sole responsibility to select a particular Elkem Silicones 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 labelling.

Packaging

SILBIONE® BIOMEDICAL HCRs are available in:

- 5 kg and 20 kg Kits. Each containing equal portions of Part A and Part B.

Storage and shelf life

When stored in their original packaging at a temperature of between 5°C (40°F) and 32°C (90°F), **SILBIONE® BIOMEDICAL HCRs** may be stored for up to 1 year from their date of manufacture. Comply with the storage instructions and expiry date marked on the packaging.

Beyond this date, Elkem Silicones no longer guarantees that the products meet the sales specifications.

Safety

Please consult the Safety Data Sheets of **SILBIONE BIOMEDICAL HCRs**.

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Warning to the users

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