Elkem

Silicones | Delivering your potential

Introducing Silbione® Biomedical HCR for Long Term Implant Applications (>30 days)

	Typical Product	Hardness, Shore A	Tensile Strength, Psi	Elongation, %	Tear Strength, Ppi	Work Life, hr.	Appearance	Mix Ratio	Specific Gravity
Typical Properties	ASTM	D2240	D412	D412	D624 Die B	D412	TP 038	-	TP 013
	HCRA M520	20	1250	1000	225	2	Clear	1:1	1.11
	HCRA M530	30	1700	1000	250	3	Clear	1:1	1.12
	HCRA M540	40	1650	975	250	4	Clear	1:1	1.13
	HCRA M550	50	1650	950	300	4	Clear	1:1	1.14
	HCRA M560	60	1550	775	265	4	Clear	1:1	1.15
	HCRA M565	65	1500	725	250	4	Clear	1:1	1.17
	HCRA M570	70	1450	700	235	4	Clear	1:1	1.18
	HCRA M580	80	1250	650	225	4	Clear	1:1	1.20

The typical properties listed above are not intended for use in preparing specifications for any particular application of Elkem Silicones' materials. All reported typical properties are press cured 5 mins. @ 177°C.
Silbione® is a registered trademark of ElkemSilicones. Note: User has sole responsibility to determine product suitability for intended uses and applications.

Silbione® Biomedical brand materials have been tested for biocompatibility according to ISO 10993/USP Class VI. Typical testing includes 12-week implant, Hemolysis, USP Intracutaneous Reactivity, USP Acute Systemic Toxicity, Cytotoxicity, Mutagenicity, Pyrogenicity, Skin Sensitization, and Tissue Irritation studies. Masterfiles (MAF) for these products are on file with the FDA.

For more information, call **1-866-474-6342** or visit our web site at **www.silbione.com.**

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Biocompatibility	Silbione® Product	Biocompatibility Tests(1)													
		EP 3.1.9	Cytotoxicity	Skin Sensitization	Skin Irritation	Intracutaneous Toxicity	Systemic Toxicity	Mutagenicity	Hemolysis	Mucosal Irritation	Pyrogenicity (USP)	12-Week Implant	USP Class VI	ISO 10993	MAF
	HCRA M520		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M530		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M540		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M550	■	■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M560		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M565		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M570		■	■	■	■	■	■	■	■	■	■	■	■	■
	HCRA M580		■	■	■	■	■	■	■	■	■	■	■	■	■

(1) -The biocompatibility testing listed addresses the categories of evaluation specified in ISO 10993 for implant device use of greater than 30 days duration
(2) - Supported by testing meeting European Pharmacopoeia section 3.1.9 hexane extraction

All testing conducted on cured LSR product A+B
■ Indicates test performed on the material; successfully passed.

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