

Silbione® HCR

for food contact, pharmaceutical contact and health care applications

Under the Silbione® HCR brand name, Bluestar Silicones manufactures and sells a range of heat-curing elastomers specifically intended for use in:

- > food contact applications
- > health care and pharmaceutical applications

Silbione® series 71000 HCRs are silicone master batches offering advantages both for processors and end users.



Food contact



Tubing for fluid handling



Medical device components

> Meets legislation

■ For processors

These products offer optimal conditions of use:

- > **Excellent processability**
- > **Conformity with regulations:** due to their low volatile content, short post curing times still enable regulations to be met

Bluestar Silicones provides its customers on request with:

- > **Certificates of conformity** containing the results of migratory tests according to food contact protocols
- > **Reports on biological testing** for health care applications

■ For end users

These products have all the advantages:

- > **High innocuity** due to the inorganic Si-O-Si chain
- > **High level of transparency**
- > **Suitable composition:** absence of compounds affecting taste
- > **Absence of nitrosamines** either in the elastomer or in the initial compound
- > **Excellent mechanical characteristics**
- > **Outstanding physico-chemical stability**
 - wide range of use (-50 °C + 200 °C) with excellent resistance to thermal ageing and oxidising agents (oxygen, ozone, UV)
 - excellent behaviour when sterilised

Silbione® HCR

				Extrusion
				High transparency
				MM 71160 U
General characteristics	Properties	Standards	Units	
	Appearance			Transparent
	Specific Gravity	ISO R1183	(g/cm ³)	1.14
	Catalyst type			E
	Catalyst content (part)			1.25
	Post cure			4 hours at 200 °C
Mechanical properties after curing and post-curing 4 hours at 200°C	Hardness, shore A	ASTM D 2240		62
	Tensile strength	ISO R37	(MPa)	10
	Elongation at break	ISO R37	(%)	320
	Tear strength	ASTM D 624 A	(kN/m)	20
	Compression set (22 h/177°C/25%)	ASTM D 395 B	(%)	35
	Rebound resilience	ISO 4662	(%)	47

> A perfect match between characteristics / applications



Safe and biocompatible

The carefully selected components that make up Silbione® HCRs enable safe articles to be manufactured according to the criteria set down in the Pharmacopoeia. When processed under optimum conditions, the articles meet the biocompatibility criteria generally applicable to products based on silicone elastomers such as:

- > the absence of hemolysis
- > the absence of tissue and bacterial adhesion.

Silicones have these qualities due to their ability to produce non-polar surfaces which therefore have very little interaction with biological systems.

Conformity with regulation

The elastomer obtained by curing and post-curing Silbione® HCR master batch for 4 hrs at 200 °C only contains substances authorised by the following regulations:

- > France: Journal Officiel dated Nov. 25, 1992 - Brochure 1227
- > Germany: BfR Part XV Silicones
- > USA: FDA Code of Federal Regulation 21 - Chap. 177.2600

High level of transparency

Silbione® HCRs high level of transparency is achieved through the use of products with a very high level of purity enabling excellent observation of conveyed liquids.

Absence of nitrosamines

The high transparency, combined with the absence of nitrosamines in Silbione® HCR master batches, makes them ideally suited to producing articles for infant applications (baby bottle teats, soothers, toys). Tests have been performed to demonstrate the absence of nitrosamines.

Short post-curing time

Due to the low volatile content in Silbione® HCR master batches, these products conform to regulation after short post-curing cycles such as 4 hrs at 200 °C. The recommended minimum amount of air is 100 l/min per kg rubber.

Excellent mechanical characteristics

The mechanical characteristics of Silbione® 71000 series HCRs are particularly well suited to these application types:

- > Tear strength, tensile strength especially for infant applications
- > High resilience for drain and catheter applications, and peristaltic pump accessories

Molding and extrusion

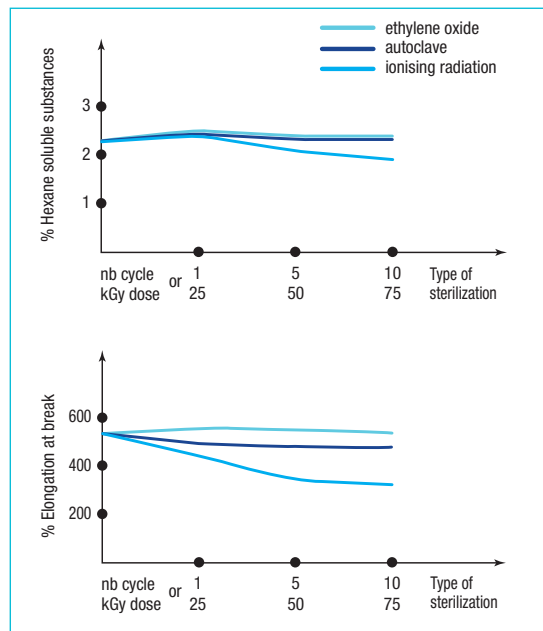
High transparency High tear strength

MM 71791/40 U	MM 71791/60 U	MM 71791/70 U
Transparent	Transparent	Transparent
1.1	1.15	1.18
E	E	E
0.9	1.25	1.25
	4 hours at 200 °C	
43	62	72
9	10	9.5
600	500	410
31	38	34
27	40	40
50	42	37

Excellent physico-chemical stability

Silbione® 71000 series HCR offer remarkable physico-chemical stability:

- > Wide range of use (-50 °C + 200 °C)
- > Very good resistance to:
 - thermal ageing
 - oxidising agents (oxygen, ozone, UV)
- > Very good behaviour in relation to all types of sterilization methods. The elastomers obtained by processing Silbione® HCR series master batches can withstand all current sterilization methods (autoclave, ethylene oxide, ionising radiation) over several cycles or at high radiation levels without significant variation in their characteristics. Even under extreme sterilizing conditions these elastomers remain in compliance with the physico-chemical tests in the European Pharmacopoeia, 3rd Edition "Silicone Elastomers for fastenings and tubing applications 3.1.9. (1997)".



Sterilization effects

In all cases, it is up to the manufacturer of the finished product to check its conformity with tests stipulated in the appropriate regulations. The use of these elastomers is prohibited by Bluestar Silicones for the following medical applications:

- > Implanted devices for more than 29 days
- > All devices in contact for more than 29 days with blood, and mucus membranes (contraception, obstetrics)
- > Plastic surgery



A Silbione® LSR range is also available. Refer to the data file Silbione® LSR

> Quality assured

Manufacturing

Bluestar Silicones takes special care in both manufacturing and quality control, which guarantee users the supply of a range of elastomers for which the quality level is in conformity with the special requirements in these applicational fields:

- > Absence of cross-contamination
- > High level of filtration
- > Specific testing

These operations are part of the Bluestar Silicones quality policy, which is ISO 9001 certified.

Testing

Specific testing is performed on each batch of products in the Silbione® HCR series in order to meet various regulations.

The results are written on the analytical certificate together with the mechanical properties.

	Pharmacopoeia specification	Food grade	Medical grade
Vulcanised, post cured product			
Identity: IR Spectrum	Conformity	●	●
Volatile content (%): (200 °C-10 g-4hrs)	0.5 max		●
Residual peroxides (%)	0.08 max		●
Mineral oils (fluorescence)	Conformity		●
Aqueous extract			
Turbidity (NTU)	4 max		●
Alkalinity (ml HCl 0.01N)	1 max		●
Acidity (ml NaOH 0.01N)	1.5 max		●
Reduc. sub. (ml Na ₂ SO ₃ 0.01N)	1 max		●
Hexane extract			
Hexane soluble (%)	3 max	●	●
Phenyl compounds (DO/UV)	0.4 max		●
Heavy metals (ppm) (other liquid extracts)	10 max	●	

> In conformity with food contact and biomedical legislation

In addition to tests performed on each batch according to the European Pharmacopoeia, Silbione® HCR master batches have directly undergone tests in relation to their application in terms of their formulation after catalysis, curing and post-curing for 4hrs at 200 °C.

Food contact / migration tests

Tests carried out in aqueous and fat-rich environments according to regulations:

- > EC Directive 82/711 and EC Directive 93/8
- > FDA: CFR 21, part 177.2600

The statements of conformity issued based on the results of these protocols are available on request.

Biological tests / biomedical applications

Performed tests required for skin contact applications in accordance with EC Directive 93/42 dated June 14, 1993 regarding medical devices:

- > Cytotoxicity
- > Skin irritation
- > Sensitization

For wound dressings, invasive devices, short term implants, blood contact applications, additional tests may have performed for certain Silbione EVC master batches according to ISO 10993 and USP class VI requirements:

- > Acute systemic toxicity
- > Intracutaneous toxicity
- > Implantation study
- > Hemolysis
- > Pyrogenicity