SILBIONE® MM SERIES 71791 U

Food contact and biomedical grade

**Description**

SILBIONE MM SERIES 71791 U are silicone rubbers which cure after addition of a vulcanising agent (chosen as a function of the production process). This series includes four products which differ by their hardness once cured: 40-50-60 and 70 Shore A.

Once processed SILBIONE MM SERIES 71791 U, "Food contact and biomedical grade" are intended for:
- biomedical applications
- applications requiring a material that is non-toxic under normal conditions of use and inert to food products.

SILBIONE MM SERIES 71791 U, are elastomers comprising polymethylvinylsiloxane gums and silica. They heat cure after addition of an organic peroxide compound. This vulcanisation must be followed by post curing at 200°C.

**Special properties**

- Easy processing
- Highly transparent
- Excellent mechanical properties, including high tear strength and a good compromise between tear strength and compression set
- Very good resistance to oxidising agents (oxygen, ozone, UV)
- Very good behaviour for all sterilisation modes
- Very good release properties
- Chemically inert

**Regulation**

The composition of SILBIONE MM SERIES 71791 U enables them to be used in conformity with the definitions in the following European and American regulations.

**Food contact:**
- **Germany:** BGVV XVA and LIIA.
- **United States:** US- FDA- CFR 21- part 177. 2600.
- **Italy:** Gazetta Ufficiale – law dated 1973 and addendum.

Moreover, samples of SILBIONE MM SERIES 71791 U, catalysed with dichloro-2, 4 benzoyle peroxide, have been subject to migration tests in accordance with European regulations: Directives 82/711/EEC and 93/8 EEC and American regulations: US-FDA- CFR 21- part 177. 2600.

**Drinking water contact**

SILBIONE MM SERIES 71791 U of hardnesses 50 and 60 ShA, have been successfully proven to be in conformity with German KTZ regulation part 1.3.13.

**Medical devices.**

Basic biological studies; cytotoxicity, irritation, sensitisation and hemocompatibility, required by directive 93/42 CE dated June 14 1993, relative to medical devices and
USP Class VI of US, have been carried out on samples of **SILBIONE MM SERIES 71791 U**, catalysed using dichloro 2,4 benzoyl peroxide.

The summaries of the biological studies are available on request.

**In all cases it is the finished article manufacturer’s responsibility to check conformity with the tests imposed by the appropriate regulations.**

For medical applications, Bluestar Silicones SAS forbids the commercialisation of these elastomers for the production of medical devices:

- Implanted for more than 29 days
- In contact for more than 29 days with blood and the mucous membranes (contraception, obstetrics)
- For plastic surgery

**Applications**

**SILBIONE MM SERIES 71791 U**, once catalysed and processed is recommended for the manufacture of the following articles:

Those which enter in contact with food such as:
- Tubes for drink distribution, including potable water
- Baby’s bottle tops
- Various technical parts.
- Sections, sleeves, calendered sheets, belts and conveyor belts

Those used in pharmacy such as:
- Tubes and piping for the circulation of liquid or soluble medicines
- Medicine conveyor belts, etc.

Those used for medical applications such as:
- Tubes and piping for extra-corporal circulation
- Oxygenotherapy tubes
- Self-injectable syringe seals

Breathing masks

**Quality Assurance**

1- **Manufacture**

Bluestar Silicones takes particular care in manufacturing and quality control in order to guarantee users with the supply of an elastomer whose quality level is in conformity with the special requirements in these types of application:

- Lack of cross-pollution.
- High level filtration.
- Specific controls.

All of these operations are part of Bluestar Silicones’ quality control policy, certified to ISO 9001.

2- **Control**

Specific controls are carried out on each batch of **SILBIONE MM SERIES 71791 U** to meet the various regulations.

The results are written on the analytical test certificate in addition to the mechanical characteristics.
SILBIONE® MM SERIES 71791 U

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>FOOD GRADE</th>
<th>MEDICAL GRADE</th>
</tr>
</thead>
<tbody>
<tr>
<td>ON POST CURED VULCANISED PRODUCT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identity : IR Spectrum</td>
<td>In Conformity</td>
<td></td>
</tr>
<tr>
<td>Volatile content (%) (200°C-10g-4h)</td>
<td>0.5 maxi.</td>
<td></td>
</tr>
<tr>
<td>Residual peroxides (%)</td>
<td>0.08 maxi.</td>
<td></td>
</tr>
<tr>
<td>Mineral oils (fluorescence)</td>
<td>In Conformity</td>
<td></td>
</tr>
<tr>
<td>ON AQUEOUS EXTRACT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Turbidity (NTU)</td>
<td>4 maxi.</td>
<td></td>
</tr>
<tr>
<td>Alkalinity (ml 0.01 M HCl)</td>
<td>1 maxi.</td>
<td></td>
</tr>
<tr>
<td>Acidity (ml 0.01 M NaOH)</td>
<td>1.5 maxi.</td>
<td></td>
</tr>
<tr>
<td>Reducing substances (ml 0.01 M Na₂SO₃)</td>
<td>1 maxi</td>
<td></td>
</tr>
<tr>
<td>ON HEXANE EXTRACT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hexane soluble (%)</td>
<td>3 maxi</td>
<td></td>
</tr>
<tr>
<td>Phenyl compounds (DO/UV)</td>
<td>0.4 maxi.</td>
<td></td>
</tr>
<tr>
<td>Heavy metals (ppm) (other than aqueous extract)</td>
<td>10 maxi</td>
<td></td>
</tr>
</tbody>
</table>

Processing methods

The choice of vulcanising agent (peroxide) to add to the SILBIONE MM SERIES 71791 U depends on the processing method and the conformity with various “Food contact grade” regulations.

The various processing methods are summarised in the table below:

<table>
<thead>
<tr>
<th>SILBIONE MM SERIES 71791 U</th>
<th>Dichloro-2, 4 benzoyle Peroxide at 50 % (E)</th>
<th>Dicumyl Peroxide at 95 % (D)</th>
<th>2, 5 dimethyl-2, 5-di (tertiobutylperoxy) hexane at 72 % (L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOULDING compression</td>
<td>0.6 PARTS PER 100 MASTER BATCH</td>
<td>0.6 PARTS PER 100 MASTER BATCH</td>
<td></td>
</tr>
<tr>
<td>injection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EXTRUSION Hot Air Vulcanisation</td>
<td>0.9 TO 1.25 PARTS PER 100 master batch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRESSURISED STEAM Vulcanisation</td>
<td>6 TO 12 BAR</td>
<td>0.6 PARTS PER 100 MASTER BATCH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>12 TO 20 BAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CALANDERING Hot Air Vulcanisation</td>
<td>0.9 TO 1.25 PARTS PER 100 master batch</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Physical properties

Type (according to AFNOR T 40002)..................................................................................MVQ

<table>
<thead>
<tr>
<th>Hardness</th>
<th>Specific gravity at 25 °C, approx.</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 ShA</td>
<td>1.10</td>
</tr>
<tr>
<td>40 ShA</td>
<td></td>
</tr>
<tr>
<td>50 ShA</td>
<td>1.13</td>
</tr>
<tr>
<td>60 ShA</td>
<td>1.15</td>
</tr>
<tr>
<td>70 ShA</td>
<td>1.18</td>
</tr>
</tbody>
</table>

Natural colour............................................................................................................Transparent

2. Mechanical properties

Below we give an example of the characteristics obtained using dichloro-2, 4 benzoyle peroxide (at 50%) as a vulcanising agent. Measurements are made on a 2 mm thick moulded sheet, cured for 8 min at 115°C and post cured for 4 hours at 200 °C.

<table>
<thead>
<tr>
<th>SILBIONE MM SERIES 71791 U</th>
<th>71 791/40 U</th>
<th>71 791/50 U</th>
<th>71 791/60 U</th>
<th>71 791/70 U</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peroxide dose in parts per 100 of master batch</td>
<td>0.9</td>
<td>1</td>
<td>1.25</td>
<td>1.25</td>
</tr>
<tr>
<td>ShA hardness , points, approx (Standard ASTM D 2240)</td>
<td>43</td>
<td>53</td>
<td>62</td>
<td>72</td>
</tr>
<tr>
<td>Tensile strength, MPa, approx. (Standard AFNOR NF T 46-002)</td>
<td>9.0</td>
<td>9.5</td>
<td>10</td>
<td>9.5</td>
</tr>
<tr>
<td>Elongation at break, %, approx. (Standard AFNOR NF T 46-002)</td>
<td>600</td>
<td>640</td>
<td>500</td>
<td>410</td>
</tr>
<tr>
<td>Tear strength, kN/m, approx. (Standard ASTM D 624 A)</td>
<td>31</td>
<td>38</td>
<td>38</td>
<td>34</td>
</tr>
<tr>
<td>Compression set (22h/177°C/25%), %, approx. (Standard ASTM D 395 B)</td>
<td>27</td>
<td>34</td>
<td>40</td>
<td>40</td>
</tr>
<tr>
<td>Rebound resilience (thickness 8 mm), %, approx. (Standard DIN 53 512)</td>
<td>50</td>
<td>45</td>
<td>42</td>
<td>37</td>
</tr>
<tr>
<td>Linear shrinkage %, approx.</td>
<td>3.5</td>
<td>3.7</td>
<td>3.7</td>
<td>4.0</td>
</tr>
</tbody>
</table>

SILBIONE MM SERIES 71791 U must be post cured at 200 °C after vulcanisation (it is recommended not to exceed this temperature).

Post curing is essential in order to:
• Ensure conformity with the legislation and regulations currently in force
• Stabilise the mechanical properties of the elastomer as well as its dimensions
• Ensure the heat stability of the elastomer
• Improve its chemical resistance, especially with respect to solvents, fats and steam
Processing

1. **Adding peroxide to SILBIONE MM SERIES 71791 U**

   This operation is performed on a two-roll mixing mill.

   **Operating procedure:**
   - Check that the equipment is scrupulously clean in order to avoid including impurities that would detract from the quality and properties of the SILBIONE MASTER BATCH.
   - Plasticise the SILBIONE MASTER BATCH.
   - Add the peroxide, then mix by cutting and crossing.
   - Cool the cylinders throughout the operation in order to maintain the SILBIONE MASTER BATCH at a temperature below 30 °C;

   In the case of catalysis using crystalised dicumyl peroxide, after dispersion it is recommended to heat the elastomer to 50 °C to ensure the fusion of the peroxide, then to cool to 30 ° once fully incorporated.

2. **Processing**

   SILBIONE MM SERIES 71791 U obtained in this way can be processed using all conventional methods in the rubber processing industry used for traditional materials.

   In this way, using SILBIONE MASTER BATCH plasticised on a two-roll mixing mill, we could:
   - Either roll a sheet to the required thickness from which we will cut preforms for moulding.
   - Or cut bands that will be used for example to feed an injection press or to prepare sheets for calendering.

3. **Vulcanisation and post curing**

   Vulcanisation of SILBIONE MM SERIES 71791 U is carried out at temperatures according to the type of peroxide used.

   Once cured we remind you that SILBIONE MM SERIES 71791 U must be post cured at 200 °C in forced air ovens with protected heating elements.

   The post cure duration depends on the thickness of the parts obtained (moulded, extruded or calendered). Post curing gives the elastomer its optimum characteristics and ensures its conformity with the requirements of the regulations currently in force.

   **Important comments:**
   - Post curing at a temperature above 200 °C or any accidental increase in temperature (e.g. to around 250-300 °C) can damage parts causing stiffening, cracking or formation of a surface glaze. It is therefore important to use good temperature control together with forced air ventilation.
   - Non-ventilated ovens or those with insufficient ventilation can cause "reversion" to occur: a reduction in hardness due to the onset of depolymerisation.
## Important notice

BLUESTAR SILICONES SAS guarantees the properties given for **SILBIONE MM SERIES 71791 U**.

However, our company cannot guarantee the behaviour of this master batch and the application that is made of it by the user, since it has no control over the conditions of application nor the process under which a study has been conducted.

## Packaging

**SILBIONE MM SERIES 71791 U** are available in 25 kg reinforced cardboard cartons. Each master batch is enclosed in a release coated sheet.

## Storage and shelf life

**SILBIONE MM SERIES 71791 U** may be stored in its original unopened packaging at a temperature below +40 °C for up to 18 months from the date of manufacture marked clearly on the packaging.

Past this date, Bluestar Silicones no longer guarantees that the product meets the sales specifications. When kept in its original unopened packaging,

According to the hardness, it is recommended to slightly refreshen **SILBIONE MM SERIES 71791 U** before using.

**Comment:** Prolonged storage beyond the recommended expiry date generally means a reduction in hardness and an increase in refreshing time.

## Safety

Please refer to the Safety Data Sheet for **SILBIONE MM SERIES 71791 U**.

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### Warning to the users

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