

## **Elastomer 42 – SILICONE ELASTOMER**

### **INSTRUCTIONS FOR USE**

#### **Introduction**

Elastomer 42 (E-42) is a low viscosity, clear material, is fully CE marked, Medical Grade supplied with a platinum catalyst and has a mixing ratio of 10 parts silicone to 1 part catalyst. The durometer of the silicone is Shore A-40.

#### **Method of Use**

For best results, ensure that the mould into which the silicone will be placed is of a good quality die stone and has been sealed accordingly.

Using a mixing ratio of 10:1 silicone / catalyst, add the catalyst to the silicone and mix thoroughly. Your silicone can now be pigmented using Cosmesil or Factor II pigments as required.

A Thixotropic Agent such as A-300-8 Factor II Thixo can be added to increase the viscosity of the material (3-4 drops per 50 grams of silicone should be sufficient), however more can be added if required. You may wish to add Thixo to a small section of your silicone material where stability in the mould is required.

#### **Packing the Mould**

Once you are satisfied with the intrinsic shading of the silicone, the mould can be packed.

Place the surface details into the mould to begin with and then fill the mould with the base shade. Overfill the mould by approximately 10%, ensuring that there is excess silicone seeping from the mould when clamped together.

When clamped, place your flask / mould into a dry oven. Take temperature up to 100°C and leave to cure for 2 hours (3 hours for a very large prosthesis).

To cure in a water bath, bring to the boil and continue at 100°C for 4 hours.

To bench cure, leave overnight at room temperature (minimum of 6-8 hours).

#### **Deflasking / Trimming**

When the prosthesis is cured, open the mould and remove carefully. The excess flash can be trimmed with sharp, pointed scissors.

For best results when trimming the silicone, use Factor II Silicone Trimming Wheels ref. 5125

**Designed for external use only. Avoid use on broken skin.**

### 1. Identification of Substance & Company:

|                                  |   |
|----------------------------------|---|
| Product Name(s)                  | Elastomer 42  |
| Product Code(s)                  | E42   |
| Medical Device Class             | Class I (according to Annex IX of EC Directive 93/42/EEC)                                 |
| Product Category /Classification | G5 (according to Annex IX of EC Directive 93/42/EEC)                                      |
| Main Use                         | Manufacture of custom prostheses  |
| Company                          | Technovent Limited<br>Bridgend Industrial Estate<br>Bridgend<br>South Wales, UK. CF31 3YH |
| Tel (& Emergency Tel )           | (44) (0) 1656 768566  |
| Fax                              | (44) (0) 1633 896588  |
| Document Version                 | 2   |
| Print Date                       | 12/07/2012  |



### 2. Composition / Information on ingredients:

|                      |  |
|----------------------|--|
| Chemical Nature      | Dispersion of fumed silica particles in platinum catalysed (ie. vinyl terminated) silicone fluid |
| Hazardous Components | None, according to EU Directive 1999/45/EC   |

### 3. Hazards Identification:

|                  |  |
|------------------|--|
| Critical Hazards | None, according to EU Directive 1999/45/EC |
|------------------|--|

### 4. First Aid Measures:

|                      |  |
|----------------------|--|
| Eye Contact          | May cause temporary irritation<br>Irrigate with water for 15 mins, holding eyelid open |
| Skin Contact         | Remove excess and wash with soap and water   |
| Inhalation of Vapour | N/a  |
| Ingestion            | May result in gastric disturbances<br>Seek medical advise                              |

### 5. Fire Fighting Measures:

|                             |      |
|-----------------------------|------|
| Hazards during firefighting | None |
|-----------------------------|------|

### 6. Accidental Release Measures:

|                           |   |
|---------------------------|---|
| Personal Protection       | Refer to Section 8  |
| Environmental Precautions | None  |
| Methods for clean-up      | Collect with tissue or likewise and dispose as Section 13 |

### 7. Handling & Storage:

|          |  |
|----------|--|
| Handling | No special precautions necessary<br>Observe good housekeeping practises (HSE guidance note CS17) |
| Storage  | Store at room temperature or refrigerated  |

### 8. Exposure Controls / Personal Protection:

|                                      |  |
|--------------------------------------|--|
| General Protective Measures          | None deemed necessary                            |
| Components with workplace parameters | None, according to EU Directive 88/379/EC        |
| Respiratory Protection               | Not deemed necessary                             |
| Hand Protection                      | Not deemed necessary, gloves recommended         |
| Eye Protection                       | Not deemed necessary, eye glasses recommended    |
| Skin Protection                      | Not deemed necessary                             |
| Hygiene Measures                     | Do not eat, drink or smoke when handling product |

### 9. Physical & Chemical Properties:

|                  |                |
|------------------|----------------|
| Physical Form    | Viscous fluid  |
| Colour           | Clear          |
| Odour            | None           |
| Flash Point      | Not determined |
| Vapour pressure  | N/a            |
| Relative Density | Not determined |
| pH               | Not determined |
| Viscosity        | Not determined |

### 10. Stability & Reactivity:

|  |   |
|--|---|
| The product is stable under normal storage conditions (refer to Section 7) |   |
| Incompatible materials   | Presence of sulphur may interfere with proper curing reaction |

### 11. Toxicological Information:

Long term experience of this product indicates no danger to health when used correctly

### 12. Ecological Information:

|                         |  |
|-------------------------|--|
| Degradation/elimination | Product does not degrade                                       |
| Bioaccumulation         | No evidence for bioaccumulation                                |
| Ecotoxic effects        | This product is not classified as Dangerous to the Environment |

### 13. Disposal Considerations:

|  |                                |
|--|--------------------------------|
| Waste product should not be discharged directly into drains or waterways.                  |                                |
| Disposal of product and packaging should always comply with local and national regulations |                                |
| EU waste code number   | No Waste Code Number available |

### 14. Transport Information:

This product is not classified as Dangerous for Carriage

### 15. Regulatory Information:

|        |                          |
|--------|--------------------------|
| Symbol | Not subject to labelling |
|--------|--------------------------|

### 16. Other Information:

All information given in this Health & Safety Data Sheet is to the best of our knowledge true and accurate and is provided solely for making safety assessments. It is not a sales specification or an indication of suitability for a particular use nor does it replace the need for your own risk assessment. All information presented in accordance with EC Directive 2001/58/EC and is correct at date of publication and is given in good faith but without warranty. We cannot accept liability for any loss, damage or patent infringement resulting from the use of this information. As with all materials, care should be exercised when handling.