TEK-SIL 25 – SILICONE ELASTOMER

INSTRUCTIONS FOR USE

Introduction

Tek-Sil 25 (S-25) is a low viscosity, clear material, supplied with a platinum catalyst and has a mixing ratio of 9 parts silicone to 1 part catalyst. The durometer of the silicone is Shore A-25.

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 9:1 silicone / catalyst, add the catalyst to the silicone and mix thoroughly. Your silicone can now be pigmented using Technovent 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)	Tek-Sil 25
Product Code(s)	S-25
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 5 York Park Bridgend South Wales, UK. CF31 3TB
Tel (& Emergency Tel)	(44) (0) 1656 768566
Fax	(44) (0) 1656 768566
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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 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 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 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.

Technovent Limited, 5 York Park, Bridgend, South Wales, UK. CF31 3TB
Tel: (44) (0) 1656 768566 Fax: (44) (0) 1656 650780 email: info@technovent.com