

Softening Agent (M513) [Page 1 of 1]

Overview

M511 softener has been specially developed to reduce the hardness of cured M511 maxillofacial silicone rubber.

Typically the addition of the maximum amount of softener will reduce the hardness of the standard rubber from 25-30 Shore A to 15-20 Shore A.

User Instructions

The softener should be added at the same time as part B of the M511 maxillofacial silicone rubber and mixed thoroughly.

The maximum amount of softener added should never exceed the amount of part B added: e.g. if 10g of part A is weighed out 1g of part B should be added and a maximum of 1g of softener can also be added

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1. Identification of Substance & Company:

Product Name(s)	Softening Agent
Product Code(s)	M513
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 Unit 5 Kingsway Buildings Bridgend South Wales, UK. CF31 3YH
Tel (& Emergency Tel)	(44) (0) 1656 768566
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Document Version	2
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2. Composition / Information on ingredients:

Chemical Nature	Dispersion of hydride functional 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
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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
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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
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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.