





# Softening Agent (M513) [Sayfa 1 of 1]

#### Genel Bakış

M511 yumuşatıcı, M511 maksillofasiyal silikon'un sertliğini azaltmak için özel olarak geliştirilmiştir.

Tipik olarak, maksimum yumuşatıcı miktarının eklenmesi standart silikonun sertliğini 25-30 Shore A'dan 15-20 Shore A'ya düşürür.

#### Kullanım Talimatları

Yumuşatıcı, M511 maksillofasiyal silikon'un Part B'si ile aynı anda eklenmeli ve iyice karıştırılmalıdır.

Eklenen maksimum yumuşatıcı madde miktarı, eklenen Part B miktarını asla geçmemelidir; 10 gr Part A tartıldığında, 1 gr Part B eklenmeli ve maksimum 1 gr yumuşatıcı eklenmelidir.



### Health & Safety Data Sheet

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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

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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

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

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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.

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