

**617H43 - Silicone Gel**

Material number 617H43

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**1. Product and company identification****Product identifier**

Trade name: 617H43 - Silicone Gel

**Relevant identified uses of the substance or mixture and uses advised against**General use: silicone rubber for orthopedic procedures.  
Reserved for industrial and professional use.**Details of the supplier of the safety data sheet**Company name: Otto Bock Health Care  
Street/POB-No.: 3820 W. Great Lakes Drive  
Postal Code, city: Salt Lake City, UT 84120  
USA

WWW: www.ottobockus.com

Telephone: +1 (801) 956-2400

Telefax: +1 (801) 956-2401

Dept. responsible for information:

Quality Department,  
Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time),  
Email: USRegulatory@ottobock.comAdditional information: Corporate headquarters:  
Ottobock SE & Co. KGaA  
Max-Näder-Straße 15  
Duderstadt  
Germany**Emergency phone number****CHEMTREC, Telephone: +1 (800) 424-9300****2. Hazards identification****Emergency overview**Appearance: Form: liquid  
Color: translucent

Odor: odorless

Classification: This material is classified as not hazardous.

**Regulatory status**

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200) and SIMDUT in Canada.

**Hazards not otherwise classified**

see section 11: Toxicological information

**3. Composition / Information on ingredients**

Chemical characterization: Polydimethylsiloxane with functional groups and supplemental additives.

## 4. First aid measures

- In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.
- Following skin contact: Immediately wipe affected skin area with paper towel or cloth. Thoroughly wash skin with soap and water. In case of skin irritation, consult a physician.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
- After swallowing: Never give anything by mouth to an unconscious person. Rinse mouth. Induce vomiting. Seek medical treatment in case of troubles.

### Most important symptoms/effects, acute and delayed

No data available

### Information to physician

Treat symptomatically.

## 5. Fire fighting measures

- Flash point/flash point range: > 482 °F (DIN 51755)
- Auto-ignition temperature: No data available
- Suitable extinguishing media: Extinguishing powder, alcohol resistant foam, carbon dioxide, dry sand.
- Extinguishing media which must not be used for safety reasons: Water

### Specific hazards arising from the chemical

In case of fire may be liberated: Carbon monoxide, carbon dioxide, Silicon dioxide.

Protective equipment and precautions for firefighters:

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: Seal off endangered area. Cool endangered containers with water spray and, if possible, remove from danger zone. Use a water fog to control vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

## 6. Accidental release measures

- Personal precautions: Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment.
- Environmental precautions: Do not allow to enter drains, surface waters, basements or pits.
- Methods for clean-up: Collect mechanically using liquid-binding material (sand, diatomaceous earth, universal binding agents). Dispose of waste in accordance with local, state, and federal regulations. Dispose of waste according to applicable legislation.

## 7. Handling and storage

### Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Precautions against fire and explosion:

Product may separate hydrogen. Potentially explosive mixture may form within partially empty containers.

Take standard precautions to prevent fire.

Specific use(s) silicone rubber for orthopedic procedures.

**Storage**

Requirements for storerooms and containers:

Keep container dry. Store only in original containers, tightly closed and in well-ventilated area. Do not drop, drag or bang the container.

Hints on joint storage: Reacts with alkalis, amines, strong acids, oxidizing agents with formation of hydrogen.

Further details: Stir well before removal or catalysation.

**8. Exposure controls / personal protection**

**Engineering controls**

Provide good ventilation and/or an exhaust system in the work area.

See also information in chapter 7, section storage.

**Personal protection equipment (PPE)**

Eye/face protection Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.

Skin protection Suitable protective clothing.  
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection is not necessary if room is well ventilated.

General hygiene considerations:

Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Have eye wash bottle or eye rinse ready at work place. Wash hands before breaks and after work. When using do not eat or drink.

**9. Physical and chemical properties**

**Information on basic physical and chemical properties**

|  |   |
|--|---|
| Appearance:                              | Form: liquid<br>Color: translucent      |
| Odor:                                    | odorless                                |
| Odor threshold:                          | No data available                       |
| pH value:                                | approx. 7                               |
| Melting point/freezing point:            | No data available                       |
| Initial boiling point and boiling range: | No data available                       |
| Flash point/flash point range:           | > 482 °F (DIN 51755)                    |
| Evaporation rate:                        | No data available                       |
| Flammability:                            | No data available                       |
| Explosion limits:                        | No data available                       |
| Vapor pressure:                          | No data available                       |
| Vapor density:                           | No data available                       |
| Density:                                 | at 77 °F: approx. 1.12 g/mL (DIN 51757) |

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|   |   |
|---|---|
| Water solubility:                       | at 68 °F: almost insoluble                  |
| Partition coefficient: n-octanol/water: | No data available                           |
| Auto-ignition temperature:              | No data available                           |
| Thermal decomposition:                  | >200°C                                      |
| Viscosity, dynamic:                     | at 73.4 °F: 1400 - 24000 mPa*s (Brookfield) |
| Ignition temperature:                   | > 842 °F (DIN 51794)                        |

**10. Stability and reactivity**

|                                    |   |
|------------------------------------|---|
| Reactivity:                        | No data available   |
| Chemical stability:                | Product is stable under normal storage conditions.  |
| Possibility of hazardous reactions | Reacts with alkalis, amines, strong acids, oxidizing agents with formation of hydrogen.<br>Potentially explosive mixture may form within partially empty containers.                                    |
| Conditions to avoid:               | Excessive heating, humidity   |
| Incompatible materials:            | Oxidizing agents, strong acids, bases   |
| Hazardous decomposition products:  | Carbon monoxide, carbon dioxide, Silicon dioxide<br>Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition. |
| Thermal decomposition:             | >200°C  |

## 11. Toxicological information

### Toxicological tests

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met. By analogy

Acute toxicity (dermal): Based on available data, the classification criteria are not met. By analogy

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Based on available data, the classification criteria are not met. By analogy

Serious eye damage/irritation: Based on available data, the classification criteria are not met. By analogy

Sensitisation to the respiratory tract: Based on available data, the classification criteria are not met. By analogy

Skin sensitisation: Based on available data, the classification criteria are not met. By analogy

Germ cell mutagenicity/Genotoxicity: Based on available data, the classification criteria are not met. By analogy

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Based on available data, the classification criteria are not met. By analogy

## 12. Ecological information

### Ecotoxicity

Aquatic toxicity: According to experience to date, toxicity to fish is not expected.

Effects in sewage plants: According to current data, no harmful effects are expected with release to sewage treatment facility.

Further details: Insoluble in water when in vulcanized state. Product is easily separated from water by filtration.

### Mobility in soil

No data available

### Persistence and degradability

Further details: Product is not biodegradable.

### Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information: Do not allow to enter into ground-water, surface water or drains.

**13. Disposal considerations**

**Product**

Recommendation: Special waste. Dispose of waste according to applicable legislation.

**Contaminated packaging**

Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

**14. Transport information**

**USA: Department of Transportation (DOT)**

Proper shipping name: Not restricted

**Sea transport (IMDG)**

Proper shipping name: Not restricted

Marine pollutant: no

**Air transport (IATA)**

Proper shipping name: Not restricted

**Further information**

No dangerous good in sense of these transport regulations.

**15. Regulatory information**

**National regulations - Great Britain**

Hazchem-Code: -

**16. Other information**

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)  
Fire: 1 (Slight)  
Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)  
Flammability: 1 (Slight)  
Physical Hazard: 0 (Minimal)  
Personal Protection: B

|                 |   |
|-----------------|---|
| HEALTH          | 0 |
| FLAMMABILITY    | 1 |
| PHYSICAL HAZARD | 0 |
| B               |   |

Reason of change: Changes in section 1.3: Corporate headquarters

Date of first version: 10/15/1994

**Department issuing data sheet**

Contact person: see section 1: Dept. responsible for information

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.