

**617H44 - Silicone Gel**

Material number 617H44

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

Trade name: 617H44 - Silicone Gel

**Relevant identified uses of the substance or mixture and uses advised against**

General use: Chemical base component for the production of plastics  
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](http://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.com](mailto:USRegulatory@ottobock.com)

Additional 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**

Product may separate hydrogen.  
 Avoid contact with acids, Alkalis, amines, alcohols, water, metal salts, oxidizing agents and catalysts. keep away from ammonia.  
 Special danger of slipping by leaking/spilling product.  
 Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.  
 see section 11: Toxicological information

**3. Composition / Information on ingredients**

Chemical characterization: Polydimethylsiloxane with functional groups and supplemental additives.

**4. First aid measures**

General information: In case of accident or if you feel unwell, seek medical advice immediately.  
 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.  
 Clean contaminated area with soap and water.  
 Seek medical treatment in case of troubles.  
 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: If you feel unwell, seek medical advice.  
 Let water be drunken in little sips (dilution effect).  
 Do not induce vomiting.

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

Due to the formation of an oil film on the eye ball sight may be reversibly clouded.

**Information to physician**

Treat symptomatically.

**5. Fire fighting measures**

Flash point/flash point range:  
 > 482 °F (DIN 51755)  
 Auto-ignition temperature: > 464 °F  
 Suitable extinguishing media:  
 Alcohol resistant foam, carbon dioxide, dry sand.  
 Extinguishing media which must not be used for safety reasons:  
 Water, dry chemical powder, Halones.

**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 self-contained breathing apparatus.

Additional information:

Hydrogen could be embedded under the foam.  
 Cleaning work: Eliminate all ignition sources if safe to do so.

## 6. Accidental release measures

- Personal precautions:** Eliminate all ignition sources if safe to do so.  
Wear appropriate protective equipment.
- Environmental precautions:** Do not allow to enter drains, surface waters, basements or pits.
- Methods for clean-up:** Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.  
Store in special closed containers and dispose of according to ordinance. binder: neutral!  
Do not keep the container sealed. Final cleaning.
- Additional information:** Special danger of slipping by leaking/spilling product.

## 7. Handling and storage

### Handling

- Advices on safe handling:** Provide good ventilation and/or an exhaust system in the work area.  
Handle and open container with care.  
Keep your workplace clean.
- Precautions against fire and explosion:**  
Product may separate hydrogen. Potentially explosive mixture may form within partially empty containers.  
Keep away from sources of ignition - No smoking. Avoid open flames.  
Take precautionary measures against static discharges.

### Storage

- Requirements for storerooms and containers:**  
Keep only in the original container in a cool, well-ventilated place.  
Keep container tightly closed and dry.  
Store under protective gas (nitrogen). Store to the exclusion of humidity.  
Do not store in containers of new glass with an alkaline surface.
- Hints on joint storage:** Avoid contact with acids, Alkalis, amines, alcohols, water, metal salts, oxidizing agents and catalysts. keep away from ammonia.  
Product may separate hydrogen.
- Further details:** Stir well before removal or catalysation.

## 8. Exposure controls / personal protection

### Engineering controls

- Provide adequate ventilation, and local exhaust as needed.  
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** Wear suitable protective clothing.  
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
Glove material: butyl caoutchouc (butyl rubber), neoprene.  
Breakthrough time: < 60 min.  
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: When vapors form (Hydrogen): If the concentration is exceeded, closed-circuit breathing apparatus must be used!  
Do not breathe vapors.

General hygiene considerations:  
When using do not eat or drink.  
Keep away from sources of ignition - No smoking. Avoid open flames.  
Keep your workplace clean.  
Wash hands before breaks and after work.  
Take precautionary measures against static discharges.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Appearance:	Form: liquid 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:	LEL (Lower Explosion Limit): (Hydrogen) 4.00 Vol-% UEL (Upper Explosive Limit): (Hydrogen) 75.60 Vol-%
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: 1.23 g/mL (DIN 51757)
Water solubility:	at 68 °F: insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 464 °F
Thermal decomposition:	> 200°C Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.
Viscosity, dynamic:	at 73.4 °F: 3000 - 8000 mPa*s (Brookfield)
Ignition temperature:	> 842 °F (DIN 51794)
Additional information:	Spontaneous ignition at: < 464 °F on basis with catalytic effect, e.g. insulating material.

## 10. Stability and reactivity

Reactivity: refer to 10.3

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions

Product may separate hydrogen.  
Potentially explosive mixture may form within partially empty containers.  
Impurities may cause catalytic decomposition (see subsection 10.5).

Conditions to avoid:

Protect from moisture contamination.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.

Incompatible materials:

Reacts violently with acids, alkalis, amines, ammonia.  
Reacts with: alcohols, water, humidity, oxidizing agents, metal salts, catalysts, rust, impurity.

Hazardous decomposition products:

Hydrogen, Silicon dioxide, Carbon monoxide and carbon dioxide, Formaldehyde.

Thermal decomposition:

> 200°C  
Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

## 11. Toxicological information

### Toxicological tests

Toxicological effects:

Acute toxicity (oral): Based on available data, the classification criteria are not met.  
Acute toxicity (dermal): Lack of data.  
Acute toxicity (inhalative): Lack of data.  
Skin corrosion/irritation: Based on available data, the classification criteria are not met.  
Specific symptoms in animal studies, Rabbit: Not an irritant (By analogy)  
Serious eye damage/irritation: Based on available data, the classification criteria are not met.  
Specific symptoms in animal studies, Rabbit: Not an irritant (By analogy)  
Sensitisation to the respiratory tract: Lack of data.  
Skin sensitisation: Based on available data, the classification criteria are not met.  
Specific symptoms in animal studies, Guinea pig: not sensitising (OECD 406, By analogy)  
Germ cell mutagenicity/Genotoxicity: Lack of data.  
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: Lack of data.

Other information:

Not an irritant (By analogy). Not known to cause sensitization.  
Physiologically benign according to current data (not a mutagen, carcinogen or teratogen).  
Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.  
Formaldehyde vapor is harmful by inhalation and irritating to eyes and respiratory system at breathing concentration less than one part per million (1ppm).

### Symptoms

Due to the formation of an oil film on the eye ball sight may be reversibly clouded.

## 12. Ecological information

### Ecotoxicity

- Aquatic toxicity: According to experience to date, toxicity to fish is not expected.  
Forms a thin oil film on water surfaces. Separation by sedimentation.
- 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.  
No indication of bioaccumulation potential.

### 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 penetrate into soil, waterbodies or drains.

## 13. Disposal considerations

### Product

- Recommendation: Incinerate as hazardous waste according to applicable local, state, and federal regulations.

### Contaminated packaging

- Recommendation: Dispose of waste according to applicable legislation.  
Empty carefully and completely, if possible.

## 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 - U.S. Federal Regulations**

Substance/product listed in the following inventories: TSCA

**National regulations - Canada**

Substance/product listed in the following inventories: DSL

**National regulations - Great Britain**

Hazchem-Code: -

**16. Other information**

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)

Fire: 1 (Slight)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 1 (Slight)

Physical Hazard: 1 (Slight)

Personal Protection: B

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	1
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.