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
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

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.
SAFETY DATA SHEET
in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

617H44 - Silicone Gel
Material number 617H44

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Material number 617H44

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 embeded 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.
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

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.