

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 againstGeneral 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.com

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.

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- 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 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 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 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. 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 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:	Acute toxicity (oral): Lack of data.
	Acute toxicity (dermal): Lack of data.
	Acute toxicity (inhalative): Lack of data.
	Skin corrosion/irritation: Lack of data.
	Eye damage/irritation: Lack of data.
	Sensitisation to the respiratory tract: Lack of data.
	Skin sensitisation: Lack of data.
	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.

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Other information: Physiologically benign according to current data (not a mutagen, carcinogen or teratogen).
This product is not suitable for the production of medical products, categories IIa and IIb. (Directive 93/42/EEC).

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

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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: Address

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.