

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
Department 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

Transport:

CONSULTANK Lutz Harder GmbH (Contract QUALI003)

Telephone: +49 (0)178-4337434 (from USA: 01149 178 4337434)

2. Hazards identification

Emergency overview

Appearance: Physical state at 68 °F and 101.3 kPa: liquid
Color: colorless, dark
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).

Hazards not otherwise classified

Product may separate hydrogen.

Avoid contact with acids, Alkalies, amines, alcohols, water, metal salts, oxidizing agents and catalysts. (Danger: Formation of hydrogen)

Product may release detonating gas.

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.

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 540-97-6	Dodecamethylcyclhexasiloxane	< 0.3 %	not classified

4. First aid measures

General information: If medical advice is needed, have product container or label at hand.

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Thoroughly wash skin with soap and water. Take off contaminated clothing and wash it before reuse. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Let water be drunken in little sips (dilution effect). Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical treatment in case of troubles.

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:

Water mist, foam, carbon dioxide.

In case of large fires: alcohol resistant foam or aqueous film forming foams (AFFF).

Extinguishing media which must not be used for safety reasons:

Water, dry chemical powder, Halones.

Specific hazards arising from the chemical

On heating or in case of fire toxic gases may form.
Contact with water liberates hydrogen. Danger of explosion! Hydrogen gas can be trapped beneath the foam blanket.
Furthermore, there may develop: Silicon dioxide, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters:

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

Additional information:

Cleaning work: Eliminate all ignition sources if safe to do so. Seal off endangered area. Cool endangered containers with water spray and, if possible, remove from danger zone. Use water spray jet to knock down vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions:

Eliminate all ignition sources if safe to do so. Wear appropriate protective equipment. Avoid contact with skin and eyes. Provide adequate ventilation. Keep unprotected people away. Do not breathe vapors. Plug leak if safely possible.

Environmental precautions:

Do not allow to enter drains, surface waters, basements or pits. If necessary, notify appropriate authorities.

Methods for clean-up:

Soak up with absorbent materials such as sand, siliceous 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. Do not rinse down with water.

Additional information:

Use only explosion-proof equipment. Explosion protection required.
Special danger of slipping by leaking/spilling product.

7. Handling and storage

Handling

Advices on safe handling:

Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Wear appropriate protective equipment. When using do not eat, drink or smoke. Wash hands before breaks and after work. Handle and open container with care. Avoid the formation of aerosol. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place. Use a breathing protection against vapors/aerosol.

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. Vapors may form explosive mixtures with air.

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, Alkalies, amines, alcohols, water, metal salts, oxidizing agents and catalysts.
Do not store together with food.

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: Wear suitable protective clothing.
Protective gloves according to OSHA Standard - 29 CFR: 1910.138.
Glove material:
Nitrile rubber - Layer thickness: > 0.1 mm.
butyl caoutchouc (butyl rubber) - Layer thickness: > 0.3 mm.
Breakthrough time: > 480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection: Respiratory protection in case of aerosol or vapor formation.
The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particulates) that may arise when handling the product.

General hygiene considerations:
When using do not eat or drink.
Keep away from sources of ignition - No smoking. Avoid open flames.
Wash hands before breaks and after work.
Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance: Physical state at 68 °F and 101.3 kPa: liquid
Color: colorless, dark

Odor: odorless

Odor threshold: No data available

pH: 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): 4.00 Vol-% (Hydrogen) UEL (Upper Explosive Limit): 75.60 Vol-% (Hydrogen)
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: 1.23 g/mL (DIN 51757)
Water solubility:	insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 464 °F
Thermal decomposition:	> 392 °F 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: 3,000 - 8,000 mPa*s (Brookfield)
Ignition temperature:	> 842 °F (DIN 51794)
Additional information:	Spontaneous ignition at: < 464 °F on a catalytically active substrate, e.g. insulating material.

10. Stability and reactivity

Reactivity:	Product may separate hydrogen. Danger of explosion!
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	Reacts with acids, bases, water, alcohols, oxidizing agents, Catalyst with formation of hydrogen gas. 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.
Incompatible materials:	Oxidizing agents, strong acids, bases, alcohols, metal salts, water, rust, impurity.
Hazardous decomposition products:	With exposure to incompatible materials, product will release hydrogen.
Thermal decomposition:	> 392 °F 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

Acute toxicity:	LD50 Rat, oral (By analogy): > 2,000 mg/kg
	LD50 Rat, dermal (By analogy): > 2,000 mg/kg

Toxicological effects:

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

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

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.

12. Ecological information

Ecotoxicity

Aquatic toxicity: No negative effects on water organisms.
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: For the silicone component: not bio-degradable
Separation by sedimentation.

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: Incinerate as hazardous waste according to applicable local, state, and federal regulations. Dispose of waste according to applicable legislation.

Package

Recommendation: Dispose of waste according to applicable legislation.
Empty carefully and completely, if possible.
Handle contaminated packages in the same way as the substance itself.
Non-contaminated packages may be recycled.

14. Transport information

UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

Environmental hazards

Marine pollutant: no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

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 - U.S. State Regulations

No data available

National regulations - Canada

Product: Substance/product listed in the following inventories: DSL

Dodecamethylcyclohexasiloxane: DSL: listed

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	

Abbreviations and acronyms:

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
 AFFF: Aqueous film forming foams
 AS/NZS: Australian Standards/New Zealand Standards
 CAS: Chemical Abstracts Service
 CFR: Code of Federal Regulations
 CLP: Classification, Labelling and Packaging
 DMEL: Derived minimal effect level
 DNEL: Derived no-effect level
 EC: European Community
 EmS: Emergency Response Procedures for Ships Carrying Dangerous Goods
 EN: European Standard
 EQ: Excepted quantities
 IATA: International Air Transport Association
 IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
 IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
 IMDG Code: International Maritime Dangerous Goods Code
 IMO: International Maritime Organization
 LD50: Lethal dose 50%
 LEL: Lower Explosion Limit
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 SVHC: Substance of very high concern
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative

Reason of change: General revision

Date of first version: 10/15/1994



SAFETY DATA SHEET

according to 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Material number 617H44

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Department issuing data sheet

Contact person: see section 1: Department 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.