

1. Product and company identification

Product identifier

Trade name: 617H45 - Catalyst for 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
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

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: 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: Immediately clean with water and soap followed by thorough rinsing. Seek medical treatment in case of troubles.
After eye contact: Immediately flush eyes with plenty of flowing water for 5 minutes holding eyelids apart. Subsequently consult an ophthalmologist.
After swallowing: Seek medical treatment in case of troubles. Never give anything by mouth to an unconscious person. Let water be drunken in little sips (dilution effect). Do not induce vomiting.

Most important symptoms/effects, acute and delayed

No data available

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range: > 392 °F (DIN 51755)
Auto-ignition temperature: No data available
Suitable extinguishing media: Dry chemical powder, alcohol resistant foam, Water mist, dry sand, carbon dioxide.
Extinguishing media which must not be used for safety reasons: Full water jet

Specific hazards arising from the chemical

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: 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:	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Change contaminated clothing. Provide fresh air. Keep unprotected people away.
Environmental precautions:	Do not allow to penetrate into soil, waterbodies or drains. If necessary, notify appropriate authorities.
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. Final cleaning. Dispose of waste according to applicable legislation. Remove residual product with water and detergent.
Additional information:	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 the formation of aerosol. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Change contaminated clothing. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.
Precautions against fire and explosion:	Take standard precautions to prevent fire.
Specific use(s)	Chemical base component for the production of plastics.

Storage

Requirements for storerooms and containers:	Store only in original containers, tightly closed and in well-ventilated area. Keep container dry. Keep in a cool place.
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

Exposure guidelines

Occupational exposure limit values:

Type	Limit value
USA: ACGIH: TWA	5 mg/m ³ (Oil mist mineral, inhalable fraction)
USA: IDLH: TWA	2,500 mg/m ³
USA: NIOSH: STEL	10 mg/m ³ (Oil mist mineral)
USA: NIOSH: TWA	5 mg/m ³ (Oil mist mineral)
USA: OSHA: TWA	5 mg/m ³ (Oil mist mineral)

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:	<p>Wear suitable protective clothing.</p> <p>Protective gloves according to OSHA Standard - 29 CFR: 1910.138.</p> <p>Glove material: Nitrile rubber - Layer thickness: 0,1 mm.</p> <p>Butyl caoutchouc (butyl rubber) - Layer thickness: 0,3 mm.</p> <p>Breakthrough time: >480 min.</p> <p>Observe glove manufacturer's instructions concerning penetrability and breakthrough time.</p>
Respiratory protection:	Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type FFP1 according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
General hygiene considerations:	Avoid contact with skin, eyes, and clothing. Change contaminated clothing. When using do not smoke. Wash hands before breaks and after work. When using do not eat or drink. 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
Odor:	odorless
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 392 °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: 0.97 g/mL (DIN 51757)
Water solubility:	at 68 °F: almost insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 73.4 °F: 1,000 mPa*s (Brookfield)
Ignition temperature:	> 842 °F (DIN 51794)
Additional information:	Relative density 68 °F: 0,97 (DIN 51757)

10. Stability and reactivity

Reactivity:	no data available
Chemical stability:	Product is stable under normal storage conditions.
Possibility of hazardous reactions:	No dangerous reactions are known.
Conditions to avoid:	Protect from excessive heat.
Incompatible materials:	Reacts with alkalis, amines, strong acids, oxidizing agents with formation of hydrogen.
Hazardous decomposition products:	Silicon dioxide, carbon monoxide and carbon dioxide Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

Acute toxicity:	LD50 Rat, oral: > 5,000 mg/kg (By analogy) LD50 Rat, dermal: > 2,008 mg/kg (By analogy)
Toxicological effects:	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 (OECD 406) 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: According to experience to date, toxicity to fish is not expected. According to current data, no harmful effects are expected with release to sewage treatment facility.

Fish toxicity:

LC50 > 1,000 mg/L (Polydimethylsiloxane)

NOEC Rainbow trout: > 10,000 mg/L 96h (Polydimethylsiloxane)

Algae toxicity:

IC50 Skeletonema costatum: > 100,000 mg/L/72h (Polydimethylsiloxane)

Daphnia toxicity:

EC50 Daphnia magna (Big water flea): > 0.0001 mg/L/48h (Polydimethylsiloxane)

NOEC Daphnia magna (Big water flea): > 500 mg/kg 21d (Polydimethylsiloxane)

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

Mobility in soil

Soil: adsorbed

Persistence and degradability

Further details: No data available

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

Package

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

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

Substance/product listed in the following inventories: NDSL

National regulations - Great Britain

Hazchem-Code:

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16. Other information

This product is not suitable for the production of medical products, categories IIa and IIb. (Directive 93/42/EEC).

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	

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
 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
 EC50: Effective Concentration 50%
 EEC: European Economic 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
 LC50: Median lethal concentration
 LD50: Lethal dose 50%
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 MFSU: Manufacture, formulation, supply and use
 NOEC: No Observed Effect Concentration
 OEL: Occupational Exposure Limit Value
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 TLV: Threshold Limit Value
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative
 WEL: Workplace Exposure Limit

Reason of change:

Changes in section 8: Occupational exposure limit values

Date of first version:

10/15/1994

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.