

1. 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
Zip 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 telephone number

CHEMTREC, Telephone: +1 (800) 424-9300

2. Hazard identification

Classification of the substance or mixture

This material is classified as not hazardous.

Label elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Other hazards

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.

3. Composition/information on ingredients

Mixtures

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

Suitable (and unsuitable) extinguishing media

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, protective equipment and emergency procedures

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 and material for containment and cleaning up

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

Precautions for safe 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.

Conditions for safe storage, including any incompatibilities

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

Control parameters

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)

Appropriate engineering controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment (PPE)

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.

Hand protection:	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.
Eye protection:	Tightly sealed goggles according to OSHA Standard - 29 CFR: 1910.133 or ANSI Z87.1-2010.
Body protection:	Wear suitable protective clothing.
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

Physical state at 68 °F and 101.3 kPa	liquid
Color:	colorless
Odor:	odorless
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Explosion limits:	No data available
Flash point/flash point range:	> 392 °F (DIN 51755)
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	No data available
Dynamic viscosity:	at 73.4 °F: 1,000 mPa*s (Brookfield)
Water solubility:	at 68 °F: almost insoluble
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	at 77 °F: 0.97 g/mL (DIN 51757)
Vapor density:	No data available
Particle characteristics:	Not applicable

Additional information

Ignition temperature:	> 842 °F (DIN 51794)
Additional information:	Relative density at 68 °F: 0,97 (DIN 51757)

10. Stability and reactivity

Reactivity:	no data available
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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.

11. Toxicological information

Information on toxicological effects

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: Based on previous experience, 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.

Persistence and degradability

Further details: No data available

Bioaccumulative potential

Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water:

No data available

Mobility in soil

Soil: adsorbed

Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Waste treatment methods

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

DOT, IMDG, IATA-DGR: not applicable

UN proper shipping name

DOT, IMDG, IATA-DGR: Not restricted

Transport hazard class(es)

DOT, IMDG, IATA-DGR: not applicable

Packing group

DOT, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Transport in bulk according to IMO instruments

No data available

Special precautions for user

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

Further regulations, limitations and legal requirements

No data available

16. Other information

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

Revision date: 12/17/2025

Date of first version: 10/15/1994

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

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:

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
DOT: Department of Transportation's Safety Regulations (USA)
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
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

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.