

1 Identification

Product identifier

Trade name: 617H45 - Catalyst for Silicone Gel

Recommended use and restrictions on use

General use: Chemical base component for the production of plastics.
For orthopedic procedures.
Reserved for industrial and professional use.

Initial supplier identifier

Company name: Otto Bock HealthCare Canada Ltd.

Street/POB-No.: 5470 Harvester Road

Postal code, city: Burlington, ON L7L 5N5, CA

Canada

WWW: www.ottobock.ca

Email: info.canada@ottobock.com

Telephone: (800) 665-3327

Telefax: (800) 463-3659

Department responsible for information:

Mark Agro, Telephone: (800) 665-3327 (9 am - 5 pm)

Additional information:

Corporate headquarters:
Ottobock SE & Co. KGaA
Max-Näder-Straße 15
Duderstadt
Germany

Emergency telephone number

COLLECT, Telephone: (613) 996-6666

2 Hazard identification

Classification

This mixture is classified as not hazardous.

Information elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Other hazards known to the supplier with respect to the product

Special danger of slipping by leaking/spilling product.
Measurements taken at temperatures exceeding 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

3 Composition/Information on ingredients

Mixture

Chemical name: Polydimethylsiloxane with functional groups and supplemental additives.

4 First-aid measures

Description of necessary 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.

In case of 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.

In case of skin contact: Immediately clean with water and soap followed by thorough rinsing. Seek medical treatment in case of troubles.

In case of eye contact: Immediately flush eyes with plenty of flowing water for 5 minutes holding eyelids apart. Subsequently consult an ophthalmologist.

Most important symptoms and effects, whether acute or delayed

No data available

Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

5 Fire-fighting measures

Suitable and unsuitable extinguishing media

Suitable extinguishing media: Extinguishing powder, alcohol resistant foam, Water mist, dry sand, carbon dioxide.

Unsuitable extinguishing media: Full water jet

Specific hazards arising from the product

Silicon dioxide, Carbon monoxide and carbon dioxide

Special protective equipment and precautions for fire-fighters

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 vapours. 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

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
Canada: Alberta, OEL 15 min	10 mg/m ³ (Oil mist mineral)
Canada: Alberta, OEL 8 hour	5 mg/m ³ (Oil mist mineral)
Canada: BC, OEL TWA	0.2 mg/m ³ (Oil mist mineral)
Canada: BC, OEL TWA	1 mg/m ³ (Oil mist mineral, highly refined)
Canada: Québec, VEMP	5 mg/m ³ (Oil mist mineral)

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

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 20 °C and 101.3 kPa	liquid
Colour:	colourless
Odour:	odourless
Odour threshold:	No data available
Melting point and freezing point:	No data available
Boiling point or initial boiling point and boiling range:	No data available
Flammability:	No data available
Lower and upper explosion limit or lower and upper flammability limit:	No data available
Flash point/flash point range:	> 200 °C (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 23 °C: 1,000 mPa*s (Brookfield)
Water solubility:	at 20 °C: almost insoluble
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	No data available
Density and/or relative density	at 25 °C: 0.97 g/mL (DIN 51757)
Vapour density:	No data available

Particle characteristics: Not applicable

Additional information

Ignition temperature: > 450 °C (DIN 51794)

Additional information: Relative density at 20 °C: 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 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

11 Toxicological information

Information on the likely routes of exposure

No data available

Health hazard information

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.

Acute toxicity:

LD50 Rat, oral: > 5,000 mg/kg (By analogy)

LD50 Rat, dermal: > 2,008 mg/kg (By analogy)

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

TDG, IMDG, IATA-DGR: not applicable

UN proper shipping name

TDG, IMDG, IATA-DGR: Not restricted

Transport hazard class

TDG, IMDG, IATA-DGR: not applicable

Packing group

TDG, IMDG, IATA-DGR: not applicable

Environmental hazards

Marine pollutant: no

Special precautions in connection with transport or conveyance either within or outside the premises

Canada: Transportation of Dangerous Goods (TDG)

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 - Canada

Substance/product listed in the following inventories: NDSL

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: 17/12/2025

Date of first version: 15/10/1994

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)

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
 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
 TDG: Transportation of Dangerous Goods Regulation in Canada
 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.