



# SAFETY DATA SHEET

according to Hazardous Products Regulations (HPR) 2022

## 617H47 - Stabilizing Agent for Silicone Gel

Material number 617H47

Revision date: 17/12/2025  
Version: 13.2  
Replaces version: 13.1  
Language: en-CA  
Date of print: 1/6/2026

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### 1 Identification

#### Product identifier

Trade name: 617H47 - Stabilizing Agent for Silicone Gel

#### Recommended use and restrictions on use

General use: Stabilizing Agent for Silicone Gel for orthopedic procedures. Restricted to professional users.

#### 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](http://www.ottobock.ca)

Email: [info.canada@ottobock.com](mailto: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 substance 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.

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## 3 Composition/Information on ingredients

### Material/substance

Chemical name: polyglycols

## 4 First-aid measures

### Description of necessary first-aid measures

In case of inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical attention if problems persist.

In case of swallowing: Rinse mouth. Never give anything by mouth to an unconscious person. Seek medical attention.

In case of skin contact: Remove residues with soap and water. Change contaminated clothing. In case of skin reactions, consult a physician.

In case of 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. In case of eye irritation 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:

Water mist, extinguishing powder, foam, carbon dioxide

Unsuitable extinguishing media:

Full water jet

### Specific hazards arising from the product

May form dangerous gases and vapours in case of fire. Furthermore, there may develop: carbon monoxide and carbon dioxide

### Special protective equipment and precautions for fire-fighters

Wear self-contained breathing apparatus. Wear appropriate protective equipment.

Additional information:

Do not allow fire water to penetrate into surface or ground water.

## 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Do not breathe mist/vapours/spray. Provide adequate ventilation. Wear appropriate protective equipment.

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### Environmental precautions:

Do not release large quantities into the surface water or into drains.

### Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents) and place in closed containers for disposal.  
Never return spills in original containers for re-use.

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. Do not breathe mist/vapours/spray. Wear appropriate protective equipment.  
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

### Conditions for safe storage, including any incompatibilities

#### Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place.  
Keep container dry. Keep only in the original container.  
Protect from heat and direct sunlight.  
Protect from frost.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.

## 8 Exposure controls/Personal protection

### Control parameters

### 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: In case of inadequate ventilation wear respiratory protection.  
Filter type: FFP1  
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

Hand protection: Protective gloves according to OSHA Standard - 29 CFR: 1910.138.  
Glove material: nitrile rubber  
Breakthrough time: > 480 min  
Layer thickness: > 0.1 mm  
Glove material: butyl caoutchouc (butyl rubber)  
Breakthrough time: > 480 min  
Layer thickness: > 0.3 mm  
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:

Do not breathe mist/vapours/spray. Do not get in eyes, on skin, or on clothing.  
Do not eat, drink or smoke when using this product.  
Wash hands thoroughly after handling.

### 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:	yellow
Odour:	Weak
Odour threshold:	No data available
Melting point and freezing point:	Not determined
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:	> 250 °C (ISO 2592)
Evaporation rate:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
pH:	at 20 °C, 10 g/L: 6 - 8
Kinematic viscosity:	at 50 °C: 150 mm <sup>2</sup> /s
Dynamic viscosity:	at 50 °C: approx. 200 mPa*s (DIN 53015)
Water solubility:	at 20 °C: 100 g/L
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	Not determined
Density and/or relative density	at 50 °C: approx. 1.03 g/mL (DIN 51757)
Vapour density:	No data available
Particle characteristics:	Not applicable

### Additional information

Ignition temperature:	approx. 365 °C (DIN 51794)
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## 10 Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:  
No dangerous reactions with proper and specified storage and handling.

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Conditions to avoid: Protect from heat and direct sunlight. Protect from frost. Protect from moisture contamination.

Incompatible materials: Strong acids, strong bases, strong oxidizing agents

Hazardous decomposition products: No hazardous decomposition products when regulations for storage and handling are observed.

## 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.

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

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

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Specific symptoms in animal studies, Rabbit: Not an irritant

Serious eye damage/irritation: Based on available data, the classification criteria are not met.

Specific symptoms in animal studies, Rabbit: Not an irritant

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.

Acute toxicity: LD50 Rat, oral: > 2,000 mg/kg

## 12 Ecological information

### Ecotoxicity

Aquatic toxicity: Fish toxicity:  
LC50 Leuciscus idus: > 1,000 mg/L/96h

Effects in sewage plants: Do not bring higher quantities to clarification plants.

### Persistence and degradability

Further details: Biodegradability: <70 %/28 d

### Bioaccumulative potential

Partition coefficient — n-octanol/water:

No data available

### Mobility in soil

No data available

### Other adverse effects

Oxygen demand:

CSB: 1850 mg O<sub>2</sub>/g

General information:

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

## 13 Disposal considerations

### Waste treatment methods

#### Product

Recommendation:

Incinerate according to applicable local, state and federal regulations.

#### Package

Recommendation:

Dispose of waste according to applicable legislation.

Handle contaminated packages in the same way as the substance itself.

Non-contaminated packages may be recycled.

## 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

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### 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

No data available

### Further regulations, limitations and legal requirements

No data available

## 16 Other information

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

#### 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  
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  
OSHA: Occupational Safety and Health Administration  
PBT: Persistent, bioaccumulative and toxic  
PNEC: Predicted no-effect concentration  
TDG: Transportation of Dangerous Goods Regulation in Canada  
TRGS: Technical Rules for Hazardous Substances  
vPvB: Very persistent and very bioaccumulative

### 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.