

617H47 - Stabilizing Agent for Silicone Gel

Material number 617H47

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1. Product and company identification

Product identifier

Trade name: 617H47 - Stabilizing Agent for Silicone Gel

Relevant identified uses of the substance or mixture and uses advised against

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

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: yellow
Odor: Weak
Classification: This substance 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.
see section 11: Toxicological information

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3. Composition / Information on ingredients

Chemical characterization: polyglycols

4. 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.

Following skin contact: Remove residues with soap and water. Change contaminated clothing. 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. In case of eye irritation consult an ophthalmologist.

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

Most important symptoms/effects, acute and delayed

No data available

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range: > 482 °F (ISO 2592)

Auto-ignition temperature: No data available

Suitable extinguishing media: Water mist, dry chemical powder, foam, carbon dioxide

Extinguishing media which must not be used for safety reasons: Full water jet

Specific hazards arising from the chemical

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

Protective equipment and precautions for firefighters:

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

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

Methods for clean-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

Handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe mist/vapors/spray. Wear appropriate protective equipment.
Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

Storage

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

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
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.

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/vapor/aerosol/particulates) that may arise when handling the product.

General hygiene considerations:
Do not breathe mist/vapors/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".

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9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Color: yellow
Odor:	Weak
Odor threshold:	No data available
pH:	at 68 °F, 10 g/L: 6 - 8
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 482 °F (ISO 2592)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	Not determined
Vapor density:	No data available
Density:	at 122 °F: approx. 1.03 g/mL (DIN 51757)
Water solubility:	at 68 °F: 100 g/L
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity, dynamic:	at 122 °F: approx. 200 mPa*s (DIN 53015)
Viscosity, kinematic:	at 122 °F: 150 mm²/s
Ignition temperature:	approx. 689 °F (DIN 51794)

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.
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.
Thermal decomposition:	No data available

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11. Toxicological information

Toxicological tests

Acute toxicity: LD50 Rat, oral: > 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): 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.

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.

Mobility in soil

No data available

Persistence and degradability

Further details: Biodegradability: <70 %/28 d

Additional ecological information

Oxygen demand: CSB: 1850 mg O2/g

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

13. Disposal considerations

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

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

No data available

National regulations - U.S. State Regulations

No data available

16. Other information

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: X = Consult your supervisor

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
	X

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
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
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative

Reason of change:

General revision

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.