

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

Dept. responsible for information:

Quality Department,

Telephone: +1 (801) 954-2304 (7 AM – 3 PM, Mountain Time), Email:

USRegulatory@ottobock.com

Emergency phone number**CHEMTREC, Telephone: +1 (800) 424-9300****2. Hazards identification****Emergency overview**Appearance: Form: liquid
Color: colorless up to yellowish

Odor: weak

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) and SIMDUT in Canada.

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredientsChemical characterization: Ethylene oxide-propylene oxide copolymer, polyglycols
(C₃H₆O . C₂H₄O)_x = Polymerized product of propyleneoxide and ethylenoxide

CAS-Number: 9003-11-6

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4. First aid measures

- In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.
- Following skin contact: After contact with skin, wash immediately with plenty of water. In case of skin irritation, consult a physician.
- After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of troubles or persistent symptoms, consult an ophthalmologist.
- After swallowing: If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms/effects, acute and delayed

In case of ingestion: Diarrhea, Dizziness, headache, weakness.

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 fog, dry chemical powder, foam, carbon dioxide
- Extinguishing media which must not be used for safety reasons:
High power water jet

Specific hazards arising from the chemical

Combustible. In case of fire may be liberated: Carbon monoxide and carbon dioxide.

- Protective equipment and precautions for firefighters:
Wear self-contained breathing apparatus. Wear protective equipment.
- Additional information: Cool endangered containers with water spray and, if possible, remove from danger zone.
Suppress gases/vapours/mists with water spray jet.
Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

- Personal precautions: Avoid contact with the substance. Do not breathe vapors. Wear protective equipment.
- Environmental precautions:
Do not allow to enter soil, sewage, water bodies, lower level rooms or pits.
- Methods for clean-up: Plug leak if safely possible. Collect mechanically using liquid-binding material (sand, diatomaceous earth, universal binding agents). Dispose of waste in accordance with local, state, and federal regulations. Wash spill area with plenty of water.

7. Handling and storage

Handling

- Advices on safe handling: Provide adequate ventilation.
Do not breathe vapors. Wear protective equipment.
When using do not eat, drink or smoke.
Avoid contact during pregnancy/while nursing.

Precautions against fire and explosion:

Take precautionary measures against static discharges.

Storage

Requirements for storerooms and containers:

Do not store in open areas or outside. Keep container dry. Store only in original containers, tightly closed and in well-ventilated area.

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

Engineering controls

Provide good ventilation.

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: rubber - Breakthrough time: >480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Respiratory protection:

Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. Use filter type A (= against vapors of organic substances) according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.

General hygiene considerations:

Avoid contact with skin, eyes, and clothing. Take off immediately all contaminated clothing.

Do not breathe vapors. Wear protective equipment.

Wash hands before breaks and after work.

When using do not eat, drink or smoke.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance:

Form: liquid

Color: colorless up to yellowish

Odor:

weak

Odor threshold:

no data available

pH value:

at 68 °F, 10 g/L: 6 - 8

Melting point/freezing point:

<= -22 °F (DIN/ISO 3016)

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:

at 68 °F: <= 0.01 hPa

Vapor density:

no data available

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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:	>220 °C
Viscosity, dynamic:	at 73.4 °F: 1000 mPa*s at 122 °F: approx. 200 mPa*s (DIN 53015)
Viscosity, kinematic:	at 122 °F: 150 mm ² /s
Ignition temperature:	approx. 689 °F (DIN 51794)

10. Stability and reactivity

Reactivity:	No data available
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions	No dangerous reactions with proper and specified storage and handling.
Conditions to avoid:	heating, humidity
Incompatible materials:	strong acids, strong bases, strong oxidizing agents
Hazardous decomposition products:	In case of fire may be liberated: Carbon monoxide and carbon dioxide.
Thermal decomposition:	>220 °C

11. Toxicological information**Toxicological tests**

Acute toxicity:	LD50 Rat, oral: > 2000 mg/kg
	LC50 Rat, inhalative: > 5 mg/L /4 h
	LD50 Rabbit, dermal: > 5000 mg/kg

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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: Lack of data.
- Eye damage/irritation: Based on available data, the classification criteria are not met.
- Specific symptoms in animal studies, Rabbit (in-vivo): mild irritant (OECD 405)
- Sensitisation to the respiratory tract: Lack of data.
- Skin sensitisation: Lack of data.
- Specific symptoms in animal studies, Rabbit (in-vivo): not sensitising
- 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.

Other information:

- Physiologically benign according to current data (not a mutagen, carcinogen or teratogen).
- Hazardous properties cannot be excluded.

Symptoms

In case of ingestion: Diarrhea, Dizziness, headache, weakness.

12. Ecological information

Ecotoxicity

Aquatic toxicity:

- Bacterial toxicity:**
EC50: >100 mg/L
- Fish toxicity:**
Poecilia reticulata LC 0: > 500 mg/L /24h
Brachydanio rerio (zebra-fish) LC50: >1000 mg/L /96 h

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

Mobility in soil

no data available

Persistence and degradability

Degree of elimination: < 70%/28 d
Evaluation text: Zahn-Wellens test
Further details: Product is not biodegradable.

Additional ecological information

Oxygen demand: CSB: 1850 mg O₂/g
Volatile organic compounds (VOC):
0.5 % by weight
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.

Contaminated packaging

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

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

TSCA Inventory: listed; EPA flags XU
 TSCA HPVC: not listed

National regulations - Canada

DSL: listed

National regulations - Great Britain

Hazchem-Code: -

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

Reason of change: Changes in section 1: Address

Date of first version: 10/15/1994



SAFETY DATA SHEET

in accordance with 29 CFR 1910.1200 and ANSI standard Z400.1-2010

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Department issuing data sheet

Contact person: see section 1: Dept. 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.