

1. Identification

Product identifier

Trade name: 617H43 - Silicone Gel

The substance/mixture contains nanoforms.

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

General use: Silicone rubber 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

Product may separate hydrogen.
Reacts with water, acids, bases, metal salts with formation of hydrogen gas. (Formation of detonating gas)
Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.
Special danger of slipping by leaking/spilling product.

3. Composition/information on ingredients

Mixtures

Chemical characterization: Polydimethylsiloxane with functional groups and supplemental additives.

Relevant ingredients:

| CAS No. | Designation | Concentration | Classification |
|----------------|---|---------------|--|
| CAS 68909-20-6 | Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform) | 25 - 50 % | Specific Target Organ Toxicity (Repeated Exposure) - Category 2. |

The actual concentration or concentration range is withheld as a trade secret.

Additional information: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform) is embedded in the product and not available as respirable dusts.
When used as intended, the product will not present a hazard regarding the following material: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform)

4. First aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Thoroughly wash skin with soap and water.
Take off contaminated clothing and wash it before reuse. 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 troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Let water be swallowed in little sips. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical treatment in case of troubles.

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:

Water mist, foam, carbon dioxide.

In case of large fires: Alcohol resistant foam or aqueous film forming foams (AFFF).

Extinguishing media which must not be used for safety reasons:

Halones, full water jet, dry chemical powder

Specific hazards arising from the chemical

Contact with water liberates hydrogen. Danger of explosion!
Hydrogen gas can be trapped beneath the foam blanket.
On heating or in case of fire toxic gases may form. Furthermore, there may develop:
Silicon dioxide, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters

Wear self-contained positive pressure breathing apparatus and full firefighting protective clothing.

Additional information: Do not inhale explosion and combustion gases. Do not allow fire water to penetrate into surface or ground water. Contaminated fire-fighting water must be collected separately.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid breathing mist/vapors/spray. Avoid contact with skin, eyes, and clothing.
If possible, eliminate leakage. Provide adequate ventilation. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.

Environmental precautions:

Do not allow to enter into ground-water, surface water or drains.

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. Binder: neutral!
Do not keep the container sealed. Do not rinse down with water. 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. Avoid breathing mist/vapors/spray. Avoid contact with skin, eyes, and clothing.
When using do not eat, drink or smoke. Wash hands before breaks and after work. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse.

Precautions against fire and explosion:

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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 only in original container.
Protect from heat and direct sunlight. Store containers in upright position.
Do not store in containers of new glass with an alkaline surface.

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

Do not store together with: Acids, bases, oxidizing agents, metal salts.

Further details: Stir well before removal or catalysation.

8. Exposure controls/personal protection

Appropriate engineering controls

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

Personal protection equipment (PPE)

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| Respiratory protection: | In case of inadequate ventilation wear respiratory protection. Suitable respiratory protection apparatus: Half-mask with filter according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2. Recommendation: 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. |
| 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 breathing 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. Take off contaminated clothing and wash it before reuse. |

Environmental exposure controls

Refer to 6.: Section "Environmental precautions".

9. Physical and chemical properties

Information on basic physical and chemical properties

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| Physical state at 68 °F and 101.3 kPa | liquid |
| Color: | colorless dark |
| Odor: | Odorless |
| Odor threshold: | No data available |
| Melting point/freezing point: | Not determined |
| Initial boiling point and boiling range: | Not determined |
| Flammability: | This material is combustible, but will not ignite readily. |
| Explosion limits: | LEL (Lower Explosion Limit): Not determined UEL (Upper Explosive Limit): Not determined |
| Flash point/flash point range: | > 482 °F (DIN 51755) |
| Evaporation rate: | No data available |
| Auto-ignition temperature: | Spontaneous ignition at: < 464 °F on a catalytically active substrate, e.g. insulating material. |
| Decomposition temperature: | > 392 °F |
| pH: | Not applicable |

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| Dynamic viscosity: | at 73.4 °F: 14,000 - 24,000 mPa*s (Brookfield) |
| Water solubility: | Practically insoluble |
| Partition coefficient: n-octanol/water: | No data available |
| Vapor pressure: | No data available |
| Density: | at 77 °F: approx. 1.12 g/mL (DIN 51757) |
| Vapor density: | No data available |
| Particle characteristics: | Information about Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform, CAS 68909-20-6): Number based particle size distribution: Nanoparticle (primary): d50 = 30 ± 25 nm (Transmission Electron Microscopy (TEM)) Nano aggregate: d50 = 300 ± 220 nm (Transmission Electron Microscopy (TEM)) Nano agglomerate: d50 = 300 ± 250 µm (laser diffraction (Malvern master sizer)) Form: fractal - Aspect ratio: 1 - 3 :1 (Transmission Electron Microscopy (TEM)) Crystallinity: Amorphous (X-ray diffraction analysis (XRD)) Surface functionalisation/treatment: none - Particle characteristics: hydrophobic Specific surface area: 200 ± 150 m²/g |

Additional information

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|-----------------------|----------------------|
| Ignition temperature: | > 842 °F (DIN 51794) |
|-----------------------|----------------------|

10. Stability and reactivity

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| Reactivity: | Refer to subsection "Possibility of hazardous reactions". |
| Chemical stability: | Stable under recommended storage conditions. |
| Possibility of hazardous reactions: | If the product comes into contact with incompatible materials, it may release large amounts of hydrogen. Vapors may form explosive mixtures with air. |
| Conditions to avoid: | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from moisture contamination. Avoid contact with contaminated tools and objects. (Formation of hydrogen) |
| Incompatible materials: | Acids, bases, oxidizing agents, metal salts |
| Hazardous decomposition products: | 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

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Based on available data, the classification criteria are not met.
ATEmix calculated: > 2,000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.
ATEmix calculated: > 2,000 mg/kg

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 (By analogy)

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

Specific symptoms in animal studies, Rabbit: Not an irritant (By analogy)

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Based on available data, the classification criteria are not met.

Specific symptoms in animal studies, Guinea pig: not sensitising (OECD 406, By analogy)

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): Based on available data, the classification criteria are not met.

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform) is embedded in the product and not available as respirable dusts.

When used as intended, the product will not present a hazard regarding the following material: Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform)

Aspiration hazard: Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

Aquatic toxicity: No harmful effect in the area of water solubility.

Persistence and degradability

Further details: For the silicone component: Not bio-degradable. Separation by sedimentation.

Bioaccumulative potential

For the silicone component: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water:
No data available

Mobility in soil

For the silicone component: The substance is not soluble in water. Adsorption to solid soil phase is expected.

Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.

13. Disposal considerations

Waste treatment methods

Product

Recommendation: Dispose of waste according to applicable legislation. Do not allow to enter drains.

Package

Recommendation: Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

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 transport as bulk according IBC - Code.

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

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (Nanoform):

TSCA Inventory: listed; UVCB

National regulations - U.S. State Regulations

No data available

Further regulations, limitations and legal requirements

No data available

16. Other information

Revision date: 11/28/2025

Date of first version: 10/15/1994

Reason of change: 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: 1 (Slight)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 1 (Slight)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor

| | |
|-----------------|---|
| HEALTH | 0 |
| FLAMMABILITY | 1 |
| PHYSICAL HAZARD | 1 |
| | X |

Abbreviations and acronyms:

AFFF: Aqueous film forming foams
 AS/NZS: Australian Standards/New Zealand Standards
 ATEMix: Acute Toxicity Estimate of mixture
 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
 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
 LEL: Lower Explosion Limit
 MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
 OSHA: Occupational Safety and Health Administration
 PBT: Persistent, bioaccumulative and toxic
 PNEC: Predicted no-effect concentration
 STOT RE: Specific target organ toxicity - repeated exposure
 TRGS: Technical Rules for Hazardous Substances
 vPvB: Very persistent and very bioaccumulative
 XRD: X-ray diffraction analysis

Department issuing data sheet

Contact person: see section 1: Department responsible for information



SAFETY DATA SHEET

according to HCS 2024 (29 CFR 1910.1200)

617H43 - Silicone Gel

Material number 617H43

Revision date: 11/28/2025

Version: 11.1

Replaces version: 11.0

Language: en-US

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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.