

## 1. Product and company 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  
Postal Code, city: Salt Lake City, UT 84120  
USA

WWW: [www.ottobockus.com](http://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](mailto: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: colorless

dark

Odor: Odorless

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).

### Hazards not otherwise classified

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.

see section 11: Toxicological information

## 3. Composition / Information on ingredients

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.

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

Flash point/flash point range:

> 482 °F (DIN 51755)

Auto-ignition temperature: Spontaneous ignition at: < 464 °F on a catalytically active substrate, e.g. insulating material.

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:

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 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

### 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.

## Storage

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

### 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 - 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.

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.

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

Appearance:

Physical state at 68 °F and 101.3 kPa: liquid  
Color: colorless  
dark

Odor:

Odorless

Odor threshold:

No data available

pH:	Not applicable
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined
Flash point/flash point range:	> 482 °F (DIN 51755)
Evaporation rate:	No data available
Flammability:	This material is combustible, but will not ignite readily.
Explosion limits:	LEL (Lower Explosion Limit): Not determined UEL (Upper Explosive Limit): Not determined
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: approx. 1.12 g/mL (DIN 51757)
Water solubility:	Practically insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	Spontaneous ignition at: < 464 °F on a catalytically active substrate, e.g. insulating material.
Thermal decomposition:	> 392 °F
Viscosity, dynamic:	at 73.4 °F: 14,000 - 24,000 mPa*s (Brookfield)
Ignition temperature:	> 842 °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:	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.
Thermal decomposition:	> 392 °F

## 11. Toxicological information

### Toxicological tests

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.

### Mobility in soil

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

### Persistence and degradability

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

### Additional ecological information

Volatile organic compounds (VOC):

0 % by weight

General information:

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

### 13. Disposal considerations

#### 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

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 transport as bulk according IBC - Code.

#### 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

## 16. Other information

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:

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  
 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  
 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  
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail  
 STOT RE: Specific target organ toxicity - repeated exposure  
 TRGS: Technical Rules for Hazardous Substances  
 vPvB: Very persistent and very bioaccumulative

Reason of change:

Changes in section 2: Classification, labelling  
 Changes in section 3: Composition/information on ingredients  
 Changes in section 10: Stability and reactivity  
 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.