

1 Identification

Product identifier

Trade name: 617H43 - Silicone Gel

Other means of identification

The substance/mixture contains nanoforms.

Recommended use and restrictions on use

General use: Silicone rubber for orthopedic procedures.
Reserved for industrial and professional use.

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

Email: 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 mixture 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

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 150 °C 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

Mixture

Chemical name: Polydimethylsiloxane with functional groups and supplemental additives.

Hazardous ingredients:

CAS No.	Designation	Content	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) 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

Description of necessary first-aid measures

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

In case of 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.

In case of 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.

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 troubles or persistent symptoms, 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, foam, carbon dioxide.

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

Unsuitable extinguishing media:

Halones, full water jet, extinguishing powder

Specific hazards arising from the product

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.

Special protective equipment and precautions for fire-fighters

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/vapours/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

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/vapours/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

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.

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/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 - 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/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. 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

Physical state at 20 °C and 101.3 kPa

liquid

Colour:

colourless

dark

Odour:	Odourless
Odour threshold:	No data available
Melting point and freezing point:	Not determined
Boiling point or initial boiling point and boiling range:	Not determined
Flammability:	This material is combustible, but will not ignite readily.
Lower and upper explosion limit or lower and upper flammability limit:	LEL (Lower Explosion Limit): Not determined UEL (Upper Explosive Limit): Not determined
Flash point/flash point range:	> 250 °C (DIN 51755)
Evaporation rate:	No data available
Auto-ignition temperature:	Spontaneous ignition at: < 240 °C on a catalytically active substrate, e.g. insulating material.
Decomposition temperature:	> 200 °C
pH:	Not applicable
Dynamic viscosity:	at 23 °C: 14,000 - 24,000 mPa*s (Brookfield)
Water solubility:	Practically insoluble
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	No data available
Density and/or relative density	at 25 °C: approx. 1.12 g/mL (DIN 51757)
Vapour 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

Ignition temperature:	> 450 °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:	If the product comes into contact with incompatible materials, it may release large amounts of hydrogen. vapours 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 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

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.

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.

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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

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

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

Product: Substance/product listed in the following inventories: DSL

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

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:

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
DSL: Domestic Substances List
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
TDG: Transportation of Dangerous Goods Regulation in Canada
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

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.