

1 Identification

Product identifier

Trade name: 617H46 - Bonding Agent for Silicone

Other means of identification

The product contains nanoparticles.

Recommended use and restrictions on use

General use: Adhesion promotor for orthopedic procedures.
For use in industrial installations and professional treatment only.

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

Reproductive toxicity 1B May damage fertility. May damage the unborn child.

Information elements

Symbols:



Signal word: **Danger**

Hazard statements: May damage fertility. May damage the unborn child.

Precautionary statements:

- Obtain special instructions before use.
- Wear protective gloves/protective clothing/eye protection.
- IF exposed or concerned: Get medical advice/attention.
- Store locked up.
- Dispose of contents/container to hazardous or special waste collection point.

Other hazards known to the supplier with respect to the product

- With exposure to moisture, product will give off a small amount of acetic acid.
- Special danger of slipping by leaking/spilling product.

3 Composition/Information on ingredients

Mixture

Chemical name: Polydimethylsiloxane, filler auxiliaries and crosslinking agent based on acetoxysilane

Hazardous ingredients:

CAS No.	Designation	Content	Classification
CAS 68909-20-6	Silamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica	25 - 50 %	Specific Target Organ Toxicity (Repeated Exposure) 2.
CAS 17689-77-9	Triacetoxysilane	1 - 2 %	Acute Toxicity 4 (oral). Skin Corrosion 1B. Eye Damage 1.
CAS -	Impurity: Oligomeric ethyl and methylacetoxysilanes	1 - 2 %	Skin Corrosion 1B. Eye Damage 1.
CAS 93925-42-9	Silicic acid (H ₄ SiO ₄), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane	< 0.3 %	Flammable Liquid 3. Acute Toxicity 4 (oral). Acute Toxicity 4 (inhalative). Eye Damage 1. Germ cell mutagenicity 2. Reproductive toxicity 1B. Specific Target Organ Toxicity (Single Exposure) 1. Specific Target Organ Toxicity (Repeated Exposure) 1. Aquatic toxicity - chronic 2.

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

Additional information: With exposure to moisture, product will give off a small amount of acetic acid.
The maximum workplace exposure limits are, where necessary, listed in section 8.

4 First-aid measures

Description of necessary first-aid measures

- General information: If medical advice is needed, have product container or label at hand. First aider: Pay attention to self-protection! Take off contaminated clothing and wash it before reuse.
- In case of inhalation: Because of the physical shape, inhalation is not regarded as a method of exposition.

In case of swallowing:	Let water be drunken in little sips (dilution effect). Seek medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
In case of skin contact:	Remove mechanically with cloth or paper. Immediately clean with water and soap followed by thorough rinsing. In case of skin irritation, 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 eye irritation 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:

Alcohol resistant foam, extinguishing powder, water mist, dry sand, carbon dioxide

Unsuitable extinguishing media:

Full water jet

Specific hazards arising from the product

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

Measurements taken at temperatures exceeding 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

Special protective equipment and precautions for fire-fighters

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

Additional information:

Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water. Fire residuals and contaminated extinguishing water must be disposed of in accordance with the regulations of the local authorities.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid exposure. Avoid breathing mist/vapours/spray. Do not get in eyes, on skin, or on 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. In case of release, notify competent authorities.

Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal. Thoroughly clean surrounding area.

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: Obtain special instructions before use. Provide adequate ventilation, and local exhaust as needed. 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. Wear appropriate protective equipment.
Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

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: Keep container tightly closed and in a well-ventilated place. Keep container dry. Keep only in original container.
Protect from heat and direct sunlight. Store containers in upright position.

Hints on joint storage: Keep away from food, drink and animal feedingstuffs.
Do not store together with: Bases, alcohols.

8 Exposure controls/Personal protection

Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
64-19-7	Acetic acid	Canada: Alberta, OEL 15 min	37 mg/m ³ ; 15 ppm
		Canada: Alberta, OEL 8 hour	25 mg/m ³ ; 10 ppm
		Canada: BC, OEL STEL	15 ppm
		Canada: BC, OEL TWA	10 ppm
		Canada: Québec, VECD	37 mg/m ³ ; 15 ppm
		Canada: Québec, VEMP	25 mg/m ³ ; 10 ppm

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: Respiratory protection must be worn whenever the TLV (WEL) levels have been exceeded. In case of inadequate ventilation wear respiratory protection.
Recommendation: Use filter type ABEK according to OSHA Standard - 29 CFR: 1910.134 or ANSI Z88.2.
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 Breakthrough time: 60 - 120 min Glove material: 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:	Obtain special instructions before use. 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. Wear appropriate protective equipment. Take off contaminated clothing and wash it before reuse. Have eye wash bottle or eye rinse ready at work place.

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:	Form: Pasty colourless
Odour:	Stinging
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): 4.00 Vol-% (Acetic acid) UEL (Upper Explosive Limit): 17.00 Vol-% (Acetic acid)
Flash point/flash point range:	Not determined
Evaporation rate:	No data available
Auto-ignition temperature:	Not self-igniting
Decomposition temperature:	No data available
pH:	No data available
Dynamic viscosity:	1,000,000 mPa*s
Water solubility:	Practically insoluble. The product can hydrolyse.
Partition coefficient — n-octanol/water:	No data available
Vapour pressure:	No data available
Density and/or relative density	at 20 °C: 1 g/cm ³ (DIN 51757)
Vapour density:	No data available
Particle characteristics:	Not applicable

Additional information

Ignition temperature: 460 °C

10 Stability and reactivity

Reactivity: Refer to subsection "Possibility of hazardous reactions".

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:
No hazardous reaction when handled and stored according to provisions.

Conditions to avoid: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from moisture.

Incompatible materials: Bases, alcohols

Hazardous decomposition products:
Measurements taken at temperatures exceeding 150 °C have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.
With exposure to moisture, product will give off a small amount of acetic acid.

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 > 2000 mg/kg

Acute toxicity (dermal): Based on available data, the classification criteria are not met.

ATEmix > 2000 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 (OECD 404).

Evaluation in analogy to a similar product.

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

Specific symptoms in animal studies: Rabbit (OECD 405), bovine eye/corneal (in-vitro, OECD 437): Not an irritant.

Evaluation in analogy to a similar product.

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: Reproductive toxicity 1B = May damage fertility. May damage the unborn child.

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 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.

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

Other information:

With exposure to moisture, product will give off a small amount of acetic acid.

Acetic acid: Irritates skin and mucous membranes.

Information about Triacetoxymethylsilane (CAS 17689-77-9):

LD50 Rat, oral: 1,460 mg/kg

12 Ecological information

Ecotoxicity

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

Persistence and degradability

Further details: Not biodegradable. This product can be eliminated from water to a large extent by abiotic procedures, e.g. adsorption to activated sludge.

Bioaccumulative potential

Bioaccumulation is unlikely.

Partition coefficient — n-octanol/water:

No data available

Mobility in soil

No data available

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
Silaname, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica:	DSL: listed
Triacetoxyethylsilane:	DSL: listed
Acetic acid:	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:

Acute Toxicity: Acute toxicity
Aquatic toxicity - chronic: Hazardous to the aquatic environment - chronic
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
Eye Damage: Eye damage
Flammable Liquid: Flammable liquid
Germ cell mutagenicity: Mutagenicity
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
LD50: Lethal dose 50%
LEL: Lower Explosion Limit
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
MFSU: Manufacture, formulation, supply and use
OEL: Occupational Exposure Limit Value
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
PNEC: Predicted no-effect concentration
Reproductive toxicity: Reproductive toxicity
Skin Corrosion: Skin corrosion
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure
TDG: Transportation of Dangerous Goods Regulation in Canada
TLV: Threshold Limit Value
TRGS: Technical Rules for Hazardous Substances
vPvB: Very persistent and very bioaccumulative
WEL: Workplace Exposure Limit

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.