

## 1. Identification

### Product identifier

Trade name: 617H46 - Bonding Agent for Silicone

The product contains nanoparticles.

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

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

### 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](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 telephone number

CHEMTREC, Telephone: +1 (800) 424-9300

## 2. Hazard identification

### Classification of the substance or mixture

Reproductive toxicant - Category 1B May damage fertility. May damage the unborn child.

### Label 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

- 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

### Mixtures

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

Relevant ingredients:

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

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.
Following 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.
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 eye irritation consult an ophthalmologist.
After 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.

### 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:

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

Extinguishing media which must not be used for safety reasons:

Full water jet

#### Specific hazards arising from the chemical

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

Measurements taken at temperatures exceeding 302 °F have revealed that a small quantity of formaldehyde splits off through oxidative decomposition.

#### Protective equipment and precautions for firefighters

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/vapors/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

Methods for clean-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/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. 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	USA: ACGIH: STEL	37 mg/m <sup>3</sup> ; 15 ppm
		USA: ACGIH: TWA	25 mg/m <sup>3</sup> ; 10 ppm
		USA: IDLH: TWA	50 ppm
		USA: NIOSH: STEL	37 mg/m <sup>3</sup> ; 15 ppm
		USA: NIOSH: TWA	25 mg/m <sup>3</sup> ; 10 ppm
		USA: OSHA: TWA	25 mg/m <sup>3</sup> ; 10 ppm

### Appropriate engineering controls

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

### Personal protection equipment (PPE)

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/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 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/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. 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 68 °F and 101.3 kPa	liquid
Color:	Form: Pasty colorless
Odor:	Stinging
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): 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
Vapor pressure:	No data available
Density:	at 68 °F: 1 g/cm <sup>3</sup> (DIN 51757)
Vapor density:	No data available
Particle characteristics:	Not applicable

### Additional information

Ignition temperature:	860 °F
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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:	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 302 °F 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 toxicological effects

Toxicological effects:	<p>Acute toxicity (oral): Based on available data, the classification criteria are not met. ATEmix &gt; 2000 mg/kg</p> <p>Acute toxicity (dermal): Based on available data, the classification criteria are not met. ATEmix &gt; 2000 mg/kg</p> <p>Acute toxicity (inhalative): Based on available data, the classification criteria are not met.</p> <p>Skin corrosion/irritation: Based on available data, the classification criteria are not met.</p> <p>Specific symptoms in animal studies: Rabbit, Not an irritant (OECD 404).</p> <p>Evaluation in analogy to a similar product.</p> <p>Serious eye damage/irritation: Based on available data, the classification criteria are not met.</p> <p>Specific symptoms in animal studies: Rabbit (OECD 405), bovine eye/corneal (in-vitro, OECD 437): Not an irritant.</p> <p>Evaluation in analogy to a similar product.</p> <p>Sensitisation to the respiratory tract: Lack of data.</p> <p>Skin sensitisation: Lack of data.</p> <p>Germ cell mutagenicity/Genotoxicity: Lack of data.</p> <p>Carcinogenicity: Lack of data.</p> <p>Reproductive toxicity: Reproductive toxicant - Category 1B = May damage fertility. May damage the unborn child.</p> <p>Effects on or via lactation: Lack of data.</p> <p>Specific target organ toxicity (single exposure): Lack of data.</p> <p>Specific target organ toxicity (repeated exposure): Based on available data, the classification criteria are not met.</p> <p>Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica is embedded in the product and not available as respirable dusts.</p> <p>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.</p> <p>Aspiration hazard: Based on available data, the classification criteria are not met.</p>
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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 abiological procedures, e.g. adsorption to activated sludge.

### Bioaccumulative potential

Partition coefficient: n-octanol/water: Bioaccumulation is unlikely.  
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

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:

TSCA Inventory: listed; UVCB

Triacetoxyethylsilane:

TSCA Inventory: listed

Acetic acid:

TSCA Inventory: listed

Clean Air Act:

CAA SOCM Chemical: yes

Clean Water Act:

CWA Hazardous Substances: Category D;  
RQ 5000.0 lbs

Other Environmental Laws:

CERCLA: RQ 5000 lbs.

NIOSH Recommendations:

Occupational Health Guideline: 0002\*

### National regulations - U.S. State Regulations

Acetic acid: New York Right-To-Know: listed

### Further regulations, limitations and legal requirements

No data available



## 16. Other information

**Text for labeling:** Contains 25 - 50 % Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica, 1 - 2 % Triacetoxysilane, 1 - 2 % Impurity: Oligomeric ethyl and methylacetoxysilanes, < 0.3 % Silicic acid (H<sub>4</sub>SiO<sub>4</sub>), tetraethyl ester, reaction products with bis(acetyloxy)diocylstannane.

**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: 3 (Serious)

Fire: 1 (Slight)

Reactivity: 1 (Slight)

HMIS Version III Rating:

Health: 3 (Serious) - Chronic effects

Flammability: 1 (Slight)

Physical Hazard: 1 (Slight)

Personal Protection: X = Consult your supervisor



HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		1
		X

**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  
 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  
 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 toxicant: Reproductive toxicity  
 Skin Corrosion: Skin corrosion  
 STOT RE: Specific target organ toxicity - repeated exposure  
 STOT SE: Specific target organ toxicity - single exposure  
 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.