

1. Product and company 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
Postal 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 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
Form: Pasty
Color: colorless
Odor: Stinging
Classification: Reproductive toxicant - Category 1B.
Hazard 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.

Regulatory status

This material is considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

With exposure to moisture, product will give off a small amount of acetic acid.
Special danger of slipping by leaking/spilling product.
see section 11: Toxicological information

3. Composition / Information on ingredients

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	Triacetoxyethylsilane	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 ₄ SiO ₄), 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.

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

Flash point/flash point range:	Not determined
Auto-ignition temperature:	Not self-igniting
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:	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 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

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.

Storage

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

Exposure guidelines

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
64-19-7	Acetic acid	USA: ACGIH: STEL	37 mg/m ³ ; 15 ppm
		USA: ACGIH: TWA	25 mg/m ³ ; 10 ppm
		USA: IDLH: TWA	50 ppm
		USA: NIOSH: STEL	37 mg/m ³ ; 15 ppm
		USA: NIOSH: TWA	25 mg/m ³ ; 10 ppm
		USA: OSHA: TWA	25 mg/m ³ ; 10 ppm

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

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.

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.

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

Appearance:	Physical state at 68 °F and 101.3 kPa: liquid Form: Pasty Color: colorless
Odor:	Stinging
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined
Flash point/flash point range:	Not determined
Evaporation rate:	No data available
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)
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 68 °F: 1 g/cm ³ (DIN 51757)
Water solubility:	Practically insoluble. The product can hydrolyse.
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	Not self-igniting
Thermal decomposition:	No data available
Viscosity, dynamic:	1,000,000 mPa*s
Ignition temperature:	860 °F

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.
Thermal decomposition:	No data available

11. Toxicological information

Toxicological tests

<p>Toxicological effects:</p> <p>Acute toxicity (oral): Based on available data, the classification criteria are not met. ATEmix > 2000 mg/kg</p> <p>Acute toxicity (dermal): Based on available data, the classification criteria are not met. ATEmix > 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 Triacetoxyethylsilane (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.

Mobility in soil

No data available

Persistence and degradability

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

Additional ecological information

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:

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: RQ 5000 lbs.

Other Environmental Laws:

CERCLA: RQ 5000 lbs.

NIOSH Recommendations:

Occupational Health Guideline: 0002*

National regulations - U.S. State Regulations

Acetic acid:

California Proposition 65 code: -

Delaware Air Quality Management List:

DRQ: 5000 - RQ State: Federal Regulations Apply

Idaho Air Pollutant List:

Title 585: AAC: 1.25 - EL: 1.67 - OEL: 25 - Title 586: -

Massachusetts Haz. Substance codes: 2,4,5,6 F8

Minnesota Haz. Substance:

Codes: AO - Ratings: -- - Status: Title III.

New York List of Hazardous Substances:

RQ-Air: 5000 - RQ-Land: 100 - Note: No Note Associated with this chemical.

Pennsylvania Haz. Substance code: E

Washington Air Contaminant:

TWA: 10 ppm - 25 mg

16. Other information

Text for labeling:

Contains 25 - 50 % Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica, 1 - 2 % Triacetoxymethylsilane, 1 - 2 % Impurity: Oligomeric ethyl and methylacetoxysilanes, < 0.3 % Silicic acid (H₄SiO₄), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane.

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
 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
 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
 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
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 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

Reason of change:

Changes in section 2: Classification, labelling
 Changes in section 3: Composition/information on ingredients
 Changes in section 11: Toxicological information
 General revision

Date of first version:

10/15/1994



SAFETY DATA SHEET

according to 29 CFR 1910.1200 and ANSI standard Z400.1-2010

617H46 - Bonding Agent for Silicone

Material number 617H46

Revision date: 8/4/2025

Version: 11.0

Replaces version: 10.1

Language: en-US

Date of print: 9/2/2025

Page: 10 of 10

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.