

1. Identification

Product identifier

Trade name: 85H71=A - Maxosil

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

General use: HTV - Silicone for the production of prostheses with 85H71=B - Maxosil catalyst
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
Zip 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 telephone number

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

2. Hazard identification

Classification of the substance or mixture

This material is classified as not hazardous.

Label elements

Symbols: not applicable

Hazard statements: not applicable

Precautionary statements: not applicable

Other hazards

Potentially explosive vapor/air mixtures may form.

3. Composition/information on ingredients

Mixtures

Chemical characterization: HTV - Silicone

Mixture on the basis of Polymethylhydrogensiloxane and Silicon dioxide

Additional information: The maximum workplace exposure limits are, where necessary, listed in section 8.

4. First aid measures

In case of inhalation: In case of heating: In case of inhalation of decomposition products, affected person should be moved into fresh air and kept still. Seek medical treatment in case of troubles.

Following skin contact: Remove mechanically with cloth or paper. Change contaminated clothing. Thoroughly wash skin with soap and water. Seek medical treatment in case of troubles.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.
In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Rinse mouth with water. Do not induce vomiting. Seek medical treatment in case of troubles.

Most important symptoms/effects, acute and delayed

After eye contact: Mild irritant

Information to physician

Treat symptomatically.

5. Fire-fighting measures

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Water spray jet, Foam, dry chemical powder, carbon dioxide

Extinguishing media which must not be used for safety reasons:

Full water jet;

Dry chemical powder, alkaline

Specific hazards arising from the chemical

Combustible.

Potentially explosive vapor/air mixtures may form.

On heating or in case of fire toxic gases may form.

In case of fire may be liberated: highly inflammable gases (Danger of explosion!), hazardous dust, silicon dioxide, carbon monoxide and carbon dioxide.

Protective equipment and precautions for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

Additional information: Seal off endangered area. Cool endangered containers with water spray and, if possible, remove from danger zone. Use water spray jet to knock down vapors. Do not breathe fumes. Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes, and clothing. Wear suitable protective clothing.
The use of protective glasses is generally recommended when handling chemicals.

Environmental precautions:

Do not empty into drains. (Danger of explosion!)
Discharge into the environment must be avoided.

Methods and material for containment and cleaning up

Methods for clean-up: Take up mechanically, placing in appropriate containers for disposal.
Final cleaning: Fouled surfaces must be immediately cleaned with suitable solvents.
(solvents: refer to section 9, not: bases)
Thoroughly clean surrounding area. Dispose of waste according to applicable legislation.

Additional information: Remove all sources of ignition.

7. Handling and storage

Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Precautions against fire and explosion:

Keep away from sources of ignition. Potentially explosive vapor/air mixtures may form.
Take standard precautions to prevent fire.

Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep container tightly closed and in a well-ventilated place. Keep only in the original container. Do not drop, drag or bang the container. Store at room temperature.

Hints on joint storage: Keep away from strong oxidizing agents, metal salts, metal-complexes, bases.

8. Exposure controls/personal protection

Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
14808-60-7	Silicon dioxide (Quartz (SiO ₂))	USA: ACGIH: TWA	0.025 mg/m ³ (respirable fraction)
		USA: IDLH: TWA	25 mg/m ³ (respirable fraction, (cristobalite/tridymite)
		USA: IDLH: TWA	50 mg/m ³ (respirable fraction, quartz/tripoli)
		USA: NIOSH: TWA	0.05 mg/m ³ (respirable fraction)
		USA: OSHA: TWA	10 mg/m ³ / % SiO ₂ + 2 (respirable fraction)
		USA: OSHA: TWA	250 mppcf/ % SiO ₂ +5 (fine dust)
		USA: OSHA: TWA	30 mg/m ³ / % SiO ₂ + 2 (inhalable fraction)

Additional information: Silicon dioxide is embedded in the product and not available as respirable dusts.

Appropriate engineering controls

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

Personal protection equipment (PPE)

Respiratory protection: Respiratory protection is not necessary if room is well ventilated.

Hand protection: Protective gloves according to OSHA Standard - 29 CFR: 1910.138
Glove material: Polyethylene/polypropylene
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: Suitable protective clothing.

General hygiene considerations:
Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Wash hands before breaks and after work.
Have eye wash bottle or eye rinse ready at work place. When using do not eat or drink.

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	Form: pasty
Color:	translucent, colorless
Odor:	weak
Odor threshold:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flammability:	No data available
Explosion limits:	LEL (Lower Explosion Limit): Hydrogen: 4.00 Vol-% UEL (Upper Explosive Limit): Hydrogen: 74.00 Vol-%
Flash point/flash point range:	> 392 °F (c.c.)
Evaporation rate:	No data available
Auto-ignition temperature:	Hydrogen: 752 °F
Decomposition temperature:	> 200 °C
pH:	No data available
Dynamic viscosity:	at 77 °F: approx. 25,000 mPa*s
Solubility:	slightly soluble in acetone, alcohol (ethanol) partially soluble/dispersible in aliphatic hydrocarbons, aromatic hydrocarbons (toluene, xylene), chlorinated hydrocarbons
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Vapor pressure:	No data available
Density:	at 77 °F: approx. 1.12 g/cm ³

Vapor density: No data available

Particle characteristics: Not applicable

10. Stability and reactivity

Reactivity: No data available

Chemical stability: Stable under recommended storage conditions.

Possibility of hazardous reactions:

Potentially explosive vapor/air mixtures may form.

Conditions to avoid: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge.

Incompatible materials: Reacts with strong oxidizing agents.
Formation of hydrogen (max. 3 l/kg) with metal salts, metal-complexes and bases.
(Danger of explosion!)

Hazardous decomposition products:

On heating or in case of fire toxic gases may form.
In case of fire may be liberated: highly inflammable gases (Danger of explosion!),
hazardous dust, silicon dioxide, carbon monoxide and carbon dioxide.
decomposition products: hydrogen (max. 3 l/kg)

11. Toxicological information

Information on toxicological effects

Acute toxicity: LD50 Rat, oral: > 2,000 mg/kg
LD50 Rat, percutan: > 2,000 mg/kg

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met.
Acute toxicity (dermal): Based on available data, the classification criteria are not met.
Acute toxicity (inhalative): Lack of data.
Skin corrosion/irritation: Lack of data.
Serious eye damage/irritation: Lack of data.
Sensitisation to the respiratory tract: Lack of data.
Skin sensitisation: Based on available data, the classification criteria are not met.
Not known to cause sensitization.
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): Lack of data.
Aspiration hazard: Lack of data.

Symptoms

After eye contact: Mild irritant

12. Ecological information

Ecotoxicity

Further details: Bio-accumulation is not to be expected ($\log P(o/w) < 1$).

Persistence and degradability

Further details: Product is not biodegradable.
Siloxanes are removed from water by sedimentation or binding to sewage sludge.

Bioaccumulative potential

Partition coefficient: n-octanol/water:
No data available

Mobility in soil

No data available

Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

13. Disposal considerations

Waste treatment methods

Product

Recommendation: Incinerate according to applicable local, state and federal regulations.

Package

Recommendation: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

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 data available

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

Product: All ingredients of this product are listed on the TSCA inventory.

Silicon dioxide (Quartz (SiO₂)): Carcinogen Status: IARC Rating: Group 1

OSHA Carcinogen: not listed

NTP Rating: listed

NIOSH Recommendations:

Occupational Health Guideline: 0553

National regulations - U.S. State Regulations

Silicon dioxide (Quartz (SiO₂)): California Proposition 65: cancer

Further regulations, limitations and legal requirements

No data available

16. Other information

Revision date: 12/17/2025

Date of first version: 11/6/2008

Reason of change: General revision: Safety Data Sheet according to Hazardous Products Regulations (HPR) 2022

General revision: Safety Data Sheet according to HCS 2024 (29 CFR 1910.1200)

Hazard rating systems:



NFPA Hazard Rating:

Health: 1 (Slight)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 1 (Slight)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: B

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0
B	

Abbreviations and acronyms:

AS/NZS: Australian Standards/New Zealand Standards
 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
 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
 log P(o/w): Partition coefficient: octanol/water
 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
 TRGS: Technical Rules for Hazardous Substances
 TSCA: Toxic Substance Control Act
 vPvB: Very persistent and very bioaccumulative

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.