

1. Product and company identification

Product identifier

Trade name: 85H11=B - Pastasil, Component B

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

General use: Component B for RTV - Silicone 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
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: Form: pasty
Color: pink up to red

Odor: odorless

Classification: This material is classified as not hazardous.

Regulatory status

This material is not considered hazardous by the U.S. OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified

see section 11: Toxicological information

3. Composition / Information on ingredients

Chemical characterization: Product on the basis of Polysiloxane and fillers (inorganic).

Additional information: Contains silicon-hydrogen bonds

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: Change contaminated clothing.
Thoroughly wash skin with soap and water.
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.
In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Never give anything by mouth to an unconscious person. Do not induce vomiting. Rinse mouth thoroughly with water.
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

Flash point/flash point range:

> 392 °F (c.c.)

Auto-ignition temperature: > 752 °F

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

Specific hazards arising from the chemical

Combustible.

In case of fire may be liberated: highly inflammable gases (hydrogen: Danger of explosion!), 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: Do not breathe vapor. Avoid inhalation and contact with skin and eyes. Wear suitable protective clothing. Ensure adequate ventilation, especially in confined areas.

Environmental precautions:

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

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.

7. Handling and storage

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:

Take standard precautions to prevent fire.

Specific use(s)

Component B for RTV - Silicone for orthopedic procedures.

Storage

Requirements for storerooms and containers:

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

Hints on joint storage:

Keep away from food, drink and animal feedingstuffs.

8. Exposure controls / personal protection

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: Suitable protective clothing.

Protective gloves according to OSHA Standard - 29 CFR: 1910.138

Glove material: Polyethylene/polypropylene (0.5 mm)

Breakthrough time: > 480 min.

Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

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

At processing:

When vapors form, use respiratory protection. 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:

Avoid contact with skin, eyes, and clothing. Change contaminated clothing. Do not

breathe vapor. Wash hands before breaks and after work. When using do not eat or drink.

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:	Form: pasty Color: pink up to red
Odor:	odorless
Odor threshold:	No data available
pH:	No data available
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	> 392 °F (c.c.)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	at 68 °F: ≤ 0.1 hPa
Vapor density:	No data available
Density:	at 77 °F: 1.55 g/cm ³
Solubility:	soluble in: diethyl ether, aliphatic hydrocarbons, aromatic hydrocarbons (toluene, xylene), chlorinated hydrocarbons
Water solubility:	practically insoluble
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	> 752 °F
Thermal decomposition:	> 392 °F
Additional information:	No data available

10. Stability and reactivity

Reactivity:	no data available
Chemical stability:	Stable under recommended storage conditions.
Possibility of hazardous reactions:	No dangerous reactions are known.
Conditions to avoid:	Excessive heating, humidity
Incompatible materials:	No data available
Hazardous decomposition products:	In case of fire may be liberated: highly inflammable gases (hydrogen: Danger of explosion!), silicon dioxide, carbon monoxide and carbon dioxide. decomposition products: hydrogen
Thermal decomposition:	> 392 °F

11. Toxicological information

Toxicological tests

Toxicological effects:

- Acute toxicity (oral): Lack of data.
- Acute toxicity (dermal): Lack of data.
- 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: No data available

Mobility in soil

No data available

Persistence and degradability

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

Additional ecological information

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

13. Disposal considerations

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

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 data available

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

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

National regulations - U.S. State Regulations

No data available

National regulations - Great Britain

Hazchem-Code:

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16. Other information

Hazard rating systems:



NFPA Hazard Rating:

Health: 0 (Minimal)

Fire: 1 (Slight)

Reactivity: 0 (Minimal)

HMIS Version III Rating:

Health: 0 (Minimal)

Flammability: 1 (Slight)

Physical Hazard: 0 (Minimal)

Personal Protection: B

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0
B	

Abbreviations and acronyms:

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
 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
 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
 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
 RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
 TRGS: Technical Rules for Hazardous Substances
 TSCA: Toxic Substance Control Act
 vPvB: Very persistent and very bioaccumulative

Reason of change: General revision

Date of first version: 6/27/2008

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.