

1. Product and company identification

Product identifier

Trade name: 85V1 - Retrasil

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

General use: Retarder for Silicone-Vulcanizer 85H11 - Pastasil.
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: liquid
Color: beige
Odor: weak
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: Mixture on the basis of polysiloxane and silicon dioxide

Relevant ingredients:

CAS No.	Designation	Concentration	Classification
CAS 78-27-3	1-Ethynylcyclohexanol	< 5 %	Acute Toxicity - oral - Category 4. Acute Toxicity - dermal - Category 4. Eye Irritation - Category 2A.

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

4. First aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove mechanically with cloth or paper. Wash with generous amount of water and soap. 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. Rinse mouth. Do not induce vomiting without medical assistance. Seek medical treatment in case of troubles.

Most important symptoms/effects, acute and delayed

After contact with skin: Mild irritant

After eye contact: Mild irritant

Information to physician

Treat symptomatically.

5. Fire fighting measures

Flash point/flash point range:

203 °F (c.c.)

Auto-ignition temperature: No data available

Suitable extinguishing media:

Foam, Extinguishing powder, water spray jet, 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: 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: 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:** Avoid contact with skin, eyes, and clothing. Wear appropriate protective equipment. Provide fresh air.
- Environmental precautions:** Do not allow to penetrate into soil, waterbodies or drains.
- Methods for clean-up:** Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning: Fouled surfaces must be immediately cleaned with suitable solvents. (solvents: refer to section 9). 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.

Precautions against fire and explosion: Take standard precautions to prevent fire.

Specific use(s) Retarder for Silicone-Vulcanizer 85H11 - Pastasil.

Storage

Requirements for storerooms and containers: Keep container tightly closed. Do not drop, drag or bang the container. Store at room temperature.

Hints on joint storage: Do not store with strong oxidizing agents.

8. Exposure controls / personal protection

Exposure guidelines

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)

Engineering controls

Provide adequate ventilation.
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. OSHA Standard - 29 CFR: 1910.138 Protective gloves according to OSHA Standard - 29 CFR: 1910.138. Glove material: Butyl caoutchouc (butyl rubber)-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.
General hygiene considerations:	Avoid contact with skin, eyes, and clothing. When using do not eat, drink or smoke. Wash hands before breaks and after work. 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: liquid Color: beige
Odor:	weak
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:	203 °F (c.c.)
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Density:	at 77 °F: 1.075 g/mL
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
Auto-ignition temperature:	No data available
Thermal decomposition:	> 392 °F
Viscosity, dynamic:	at 77 °F: 15,000 mPa*s

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
Incompatible materials:	Strong oxidizing agents
Hazardous decomposition products:	In case of fire may be liberated: silicon dioxide, carbon monoxide and carbon dioxide.
Thermal decomposition:	> 392 °F

11. Toxicological information

Toxicological tests

Acute toxicity:	LD50 Rat, oral: (1-Ethynylcyclohexanol) 590 mg/kg LD50 Rabbit, percutan: (1-Ethynylcyclohexanol) 980 mg/kg
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: Lack of data. 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 contact with skin: Mild irritant
After eye contact: Mild irritant

12. Ecological information

Ecotoxicity

Further details:	No data available
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Mobility in soil

No data available

Persistence and degradability

Further details: Silicone-ingredient(s): not bio-degradable
1-Ethynylcyclohexanol: moderately/partially biodegradable (20-70%/28 d, OECD 302B)

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

Product: TSCA: All ingredients are listed or exempt from listing.

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

National regulations - Canada

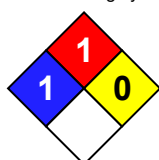
Silicon dioxide (Quartz (SiO₂)): DSL: listed
1-Ethynylcyclohexanol: DSL: listed

National regulations - Great Britain

Hazchem-Code: -

16. Other information

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:

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
 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
 Eye Irritation: Eye irritation
 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
 vPvB: Very persistent and very bioaccumulative

Reason of change: Changes in section 8: Occupational exposure limit values

Date of first version: 6/13/2008

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.