

A SILICONE HP BITE

Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code: **9790874**
Product name: **A SILICONE HP BITE**

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

Intended use: **Addition silicone for occlusion bite**

1.3. Details of the supplier of the safety data sheet

DE Healthcare Products
Gillingham ME8 0SB UK
UK +44 (0) 1634878750
Emergency : Chemtrec US (800) 424-9300
International: 001 703-527-3887
Fax +44 (0) 1634 87 87 51
for De Healthcare:
email: info@dehpbrand.com
for Cybertech:
email: info@cybertechbrand.com

2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms: --

Warning: --

Hazard indication: --

Caution recommendations:

P314 Get medical advice/attention if you feel unwell.

Contains: CRISTOBALITE
TRIDIMITE
QUARTZ

Safety data sheet available for professional users on request.

2.3. Other hazards.

Information not available.

3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

A SILICONE HP BITE**3.2. Mixtures.****Contains:**

Identification.	Conc.%. Cant	Classification 67/548/EEC.	Classification 1272/2008 (CLP).
CRISTOBALITE			
CAS. 14464-46-1	12 - 13,5	Xn R48/20	STOT RE 2 H373
EC. -			
INDEX. -			
TRIDIMITE			
CAS. 15468-32-3	12 - 13,5	Xn R48/20	STOT RE 2 H373
EC. 239-487-1			
INDEX. -			
QUARTZ			
CAS. 14808-60-7	12 - 13,5	Xn R48/20	STOT RE 2 H373
EC. 238-878-4			
INDEX. -			

T+ = Very Toxic(T+), T = Toxic(T), Xn = Harmful(Xn), C = Corrosive(C), Xi = Irritant(Xi), O = Oxidizing(O), E = Explosive(E), F+ = Extremely Flammable(F+), F = Highly Flammable(F), N = Dangerous for the Environment(N)

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

4. First aid measures.**4.1. Description of first aid measures.**

EYES: Irrigate copiously with clean, fresh water for at least 15 minutes. Seek medical advice.

SKIN: Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists, seek medical attention. Wash contaminated clothing before using them again.

INHALATION: Remove to open air. If breathing is irregular, seek medical advice.

INGESTION: Obtain immediate medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed.

For symptoms and effects caused by the contained substances see chap. 11.

4.3. Indication of any immediate medical attention and special treatment needed.

Follow doctor's orders.

5. Firefighting measures.**5.1. Extinguishing media.**

SUITABLE EXTINGUISHING MEDIA

The extinction equipment should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health.

Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with straps around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

If there are no contraindications, spray powder with water to prevent the formation of dust. Use breathing equipment if powders are released into the air.

6.2. Environmental precautions.

The product must not penetrate the sewer system, surface water, ground water and neighbouring areas.

A SILICONE HP BITE**6.3. Methods and material for containment and cleaning up.**

Use mechanical tools to collect leaked product and eliminate the remainder using jets of water. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage.**7.1. Precautions for safe handling.**

Store in closed, labelled containers.

7.2. Conditions for safe storage, including any incompatibilities.

Normal storage conditions without particular incompatibilities.

7.3. Specific end use(s).

Information not available.

8. Exposure controls/personal protection.**8.1. Control parameters.**

Name	Type	Country	TWA/8h		STEL/15min		
			mg/m3	ppm	mg/m3	ppm	
QUARTZ	TLV-ACGIH		0,025				
	OEL	IRL	0,05				
	WEL	UK	0,3				

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration or bad air vent. If such operations do not make it possible to keep the concentration of the product below the permitted workplace exposure thresholds a suitable respiratory tract protection must be used. See product label for hazard details during use. Ask your chemical substance suppliers for advice when choosing personal protection equipment. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category I (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in latex, PVC or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

EYE PROTECTION

Use of protective airtight goggles (ref. standard EN 166) recommended.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear a mask with an B or universal filter, the class (1, 2 or 3) of which must be chosen according to the limit concentration of use (ref. standard EN 141).

The use of breathing protection equipment, such as masks with organic vapour and dust/mist cartridges, is necessary in the absence of technical measures limiting worker exposure. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

In the event of prolonged worker exposure, verify the possibility of operating in a closed circuit or of reorganising the work cycle to avoid repetitive exposure; make sure the PPE used is as efficient as possible.

9. Physical and chemical properties.**9.1. Information on basic physical and chemical properties.**

Appearance	fluid
Colour	light blue
Odour	odourless
Odour threshold.	Not available.
pH.	Not available.
Melting or freezing point.	Not available.
Boiling point.	Not available.
Distillation range.	Not available.
Flash point.	Not available.

A SILICONE HP BITE

Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Specific gravity.	Not available.
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available.
Ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Reactive Properties	Not available.

9.2. Other information.

Solid content:	47,32 %
VOC (Directive 1999/13/EC) :	0
VOC (volatile carbon) :	0

10. Stability and reactivity.**10.1. Reactivity.**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information.

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled carefully according to good industrial practices. This product may have slight health effects on sensitive people, by inhalation and/or cutaneous absorption and/or contact with eyes and/or ingestion.

11.1. Information on toxicological effects.

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure by inhalation of a quantity of 0.25 mg/l/6h/day or lower.

12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

Information not available.

A SILICONE HP BITE**12.6. Other adverse effects.**

Information not available.

13. Disposal considerations.**13.1. Waste treatment methods.**

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

Point. 3

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

STOT RE 2 Specific target organ toxicity - repeated exposure, category 2
H373 May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R48/20 HARMFUL: DANGER OF SERIOUS DAMAGE TO HEALTH BY PROLONGED EXPOSURE THROUGH INHALATION.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

A SILICONE HP BITE

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.