

MATERIAL SAFETY DATA SHEET

Independence Silbond Silicone Adhesive

Technical File: TF15

Product Code: SB1



SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	Independence Silbond Silicone Adhesive
SYNONYMS:	Medical Prosthetic Adhesive
PRODUCT CODES:	SB1
MANUFACTURER:	ProSys International Ltd
DIVISION:	Regulatory Affairs - London
ADDRESS:	60 Cottenham Park Road, Wimbledon, SW20 0TB, UK
EMERGENCY PHONE:	+44 (0) 208 944 7585
CHEMTREC PHONE:	Not Applicable to UK
FAX PHONE:	+44 (0) 208 944 5434
CHEMICAL NAME:	Silicone in Solvent
PRODUCT USE:	This is a single component silicone adhesive designed for medical applications for non-permanent bonding of appliances to dry skin. The product evaporates quickly leaving a thin film with effective bonding results.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Nature Dispersion of silicone solvents in an azeotropic blend of trans-1,2 dichloro ethylene (t-DCE) and various hydrofluoroether components.

INGREDIENT	CAS Number
Trans 1,2 dichloro ethylene	156-60-5
Ethyl nonafluoroisobutyl ether	163702-06-5
Ethyl nonafluorobutyl ether	163702-05-4
Methyl nonafluorobutyl ether	163702-07-6
Methyl nonafluoroisobutyl ether	163702-08-7
Silicone solids (crosslinked polydimethylsiloxane)	68083-19-2

SECTION 3: HAZARDS IDENTIFICATION

Critical Hazards not otherwise classified None

SECTION 4: FIRST AID MEASURES

Eye Contact	May cause temporary irritation, flush with water. Irrigate with water for 15 minutes, holding eyelid open
Skin Contact	Remove excess and wash with soap and water
Inhalation of Vapour	Remove person to fresh air
Ingestion	Rinse mouth, may result in gastric disturbances. Seek medical advice
Most important symptoms & effects	See section 11
Indication of any immediate medical attention	N/A

SECTION 5: FIRE FIGHTING MEASURES

Hazards during firefighting	Exposure to extreme heat can give rise to thermal decomposition
Hazardous Decomposition by products	Carbon monoxide – during combustion Carbon dioxide – during combustion
Extinguishing media	Water or foam – treat as per ordinary combustible material

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Protection	Refer to Section 8
Environmental Precautions	Avoid release to the environment
Methods for clean-up	Collect with tissue or likewise and dispose as Section 13

SECTION 7: HANDLING & STORAGE

Handling	No special precautions necessary. Observe good housekeeping practises (HSE guidance note CS17)
Storage	Store at room temperature. Keep lid tightly closed between use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

General Protective Measures	Not deemed necessary
Respiratory Protection	Not deemed necessary
Hand Protection	Not deemed necessary, gloves recommended
Eye Protection	Not deemed necessary, however eye glasses recommended
Skin Protection	Not deemed necessary
Hygiene Measures	Do not eat, drink or smoke when handling product
Exposure	Time Weighted Average: 200ppm limit

SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

Physical Form	Liquid
Colour	Clear, colourless
Odour	Slight odour
Boiling point	43° C
Flash Point	No flash point
Vapour pressure	350 mmHg @ 25°C
Density	1.28 g/ml
pH	Not applicable
Viscosity	0.45 centipoise

SECTION 10: STABILITY AND REACTIVITY

Chemical stability	This product is stable under normal storage conditions (refer to Section 7)
Possibility of hazardous reactions	Hazardous polymerisation will not occur
Incompatible materials	Strong bases, strong oxidising agents
Conditions to avoid	If exposed to extreme conditions of heat toxic decomposition products that include hydrogen chloride, hydrogen fluoride and perfluoroisobutylene (PFIB) can occur

SECTION 11: TOXICOLOGICAL INFORMATION

Para Tertiary Butylphenol Formaldehyde is not intentionally used in this product, however patients/users that experience allergic reactions, such as redness or other forms of skin irritation, should stop using and consult their physician.

As at the date of this publication, the components contained in the secure convex baseplates and tube connectors are not listed on the Candidate List of Substances of Very High Concern (SVHC) according to the REACH Regulations.

No Animal Derived Material is used in this product or in the production process.

No Heavy Metals are incorporated in this device as listed in the RoHs Directive.

SECTION 12: ECOLOGICAL INFORMATION

Degradation/elimination	Product does not degrade
Bioaccumulation	No evidence for bioaccumulation
Ecotoxic effects	This product is not classified as Dangerous to the Environment

SECTION 13: DISPOSAL CONSIDERATIONS

Waste product should not be discharged directly into drains or waterways.

Disposal of product and packaging should always comply with local and national regulations

EU Waste Code number	18.01.07
EPA hazardous waste number (RCRA)	Not regulated

SECTION 14: TRANSPORT INFORMATION

This product is not classified as Dangerous for Carriage

SECTION 15: REGULATORY INFORMATION

MEDICAL DEVICES DIRECTIVE 93/42/EC:	Compliant
EU REACH REGULATIONS:	Compliant
EU SUBSTANCES OF VERY HIGH CONCERN (SVHC):	Compliant

SECTION 16: OTHER INFORMATION

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge at the date of its publication.

The information given is designed only as a guidance for safe handling, use, processing, storage, transportation and disposal.

Effective Date: 27th February 2017.

Version: 1

Revision Date: 26th February 2020