

MATERIAL SAFETY DATA SHEET

Independence Fusion Medical Adhesive & Barrier Film Applicator (Swab)

Technical File: TF35

Product Code: BW2



SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	Independence Fusion Medical Adhesive & Barrier Film Applicator (Swab)
SYNONYMS:	Medical Grade Silicone Adhesive
PRODUCT CODES:	BW2
MANUFACTURER:	ProSys International Ltd
DIVISION:	Regulatory Affairs - London
ADDRESS:	Suite 303, Highland House, 165 The Broadway, Wimbledon, SW19 1NE, UK
EMERGENCY PHONE:	+44 (0) 208 944 7585
CHEMTREC PHONE:	Not Applicable to UK
FAX PHONE:	+44 (0) 208 944 5434
CHEMICAL NAME:	Hexamethyldisiloxane (Silicone in Solvent)
PRODUCT USE:	A medical adhesive & barrier film applicator (swab), specifically designed for augmenting the adhesion of medical devices to the human skin. They can also be used after a total laryngectomy to increase adhesion of base plates and other skin attachment devices around the tracheostoma.
REACH REGISTRATION:	01-2119496101-31
PREPARED BY:	ProSys International Ltd
NOTE:	The data contained in this MSDS generally relates to commercial situations for storage & handling.

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	EINECS Number	Classification
Hexamethyldisiloxane (Adhesive)	107-46-0	203-492-7	Flammable Liquid 2: H225 Aquatic Acute 1: H400 Aquatic Chronic 2: H411
Extruded Polypropylene (Handle)	9002-07-0	N.A	
Polyurethane Foam (Head)	9009-54-5	N.A	

SECTION 3: HAZARDS IDENTIFICATION

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 2 H225: Highly flammable liquid and vapour

Acute aquatic toxicity, Category 1 H400: Very toxic to aquatic life.

Chronic aquatic toxicity, Category 2

H411: Toxic to aquatic life with long lasting effects.

Hazard pictograms



Highly flammable liquid and vapour.



Very toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing spray.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

SECTION 4: FIRST AID MEASURES

Protection of first-aiders

No special precautions are necessary for first aid responders.

If inhaled

Remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact

For bulk quantities, in case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.

In case of eye contact

Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed

If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing media

Water spray; Alcohol-resistant foam; Carbon dioxide (CO₂) Dry chemical

Hazardous combustion products

Carbon oxides; Silicon oxides; Formaldehyde

Special protective equipment for firefighters

Wear self-contained breathing apparatus for fire-fighting if necessary. Use personal protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions

Remove all sources of ignition. Ventilate the area. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions

Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages

SECTION 7: HANDLING & STORAGE

For warehouse operations

Ensure all equipment is electrically grounded before beginning transfer operations.

This material can accumulate static charge due to its inherent physical properties and can therefore cause an electrical ignition source to vapours.

Use with local exhaust ventilation.

Avoid inhalation of vapour or mist

Handle in accordance with good industrial hygiene and safety practice

Non-sparking tools should be used.

Keep container tightly closed.

Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Do not store with the following product types: Strong oxidizing agents; Organic peroxides; Flammable solids Pyrophoric liquids; Pyrophoric solids; Self-heating substances and mixtures; Substances and mixtures, which in contact with water, emit flammable gases; Explosives; Gases

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

For Bulk Quantities

Eye Protection	Wear the following personal protective equipment: Safety glasses
Hand protection	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub-stance and specific to place of work
Skin Protection	Flame retardant antistatic protective clothing
Respiratory Protection	Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines
Note:	For specific exposure limits for both workers and consumers, please contact ProSys International Ltd

SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

Appearance	Liquid
Colour	Clear to pale yellow
Initial boiling point	100° c
Flash Point	-1° c
Relative density	0.84
Viscosity	50cP
Explosive properties	Not explosive
Oxidizing properties	Not classified as oxidising
Reactivity	Not classified as a reactivity hazard
Chemical stability	Stable under normal conditions
Hazardous reactions	Highly flammable liquid and vapour
Conditions to avoid	Heat, flames, sparks
Thermal decomposition	Formaldehyde

SECTION 10: STABILITY AND REACTIVITY

Not classified as a reactivity hazard

Chemically stable under normal conditions

Vapours may form explosive mixture with air.

Handling operations that can promote accumulation of static charges.

SECTION 11: TOXICOLOGICAL INFORMATION

The substance or mixture has no acute oral toxicity

The substance or mixture has no acute inhalation toxicity

The substance or mixture has no acute dermal toxicity

Skin irritation - Not classified based on available information

Respiratory or skin sensitisation - Not classified based on available information

Germ cell mutagenicity - Not classified based on available information.

Carcinogenicity - Not classified based on available information.

Reproductive toxicity - Not classified based on available information.

Skin contact - No significant health effects observed in animals

Aspiration toxicity - Not classified based on available information.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicology Assessment - Toxic to aquatic life with long lasting effects

Biodegradability - Not readily biodegradable.

Mobility in soil- No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Product	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or ex-pose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

UN Number

AND	UN 1993
ADR	UN 1993
RID	UN 1993
IMDG	UN 1993
IATA	UN 1993

Shipping Name

FLAMMABLE LIQUID, .N.O.S. Hexamethyldisiloxane

Transport Hazard Class	3
Packing Group	3
Classification Code	F1
Hazard Identification Number	33
Labels	3
Environmental Hazards	Yes

SECTION 15: REGULATORY INFORMATION

REACH - Candidate List of Substances of Very High Concern	N/A
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	N/A
Regulation (EC) No 850/2004 on persistent organic pollutants	N/A
Regulation (EC) No 649/2012 on the export and import of dangerous chemicals	N/A
Medical Devices Directive 93/42/EEC	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: 10th November 2017

Version: 1

Revision Date: 10th November 2020