

MATERIAL SAFETY DATA SHEET

Independence Barrier Film Wipes

Technical File: TF18

Product Code: BW1



This data sheet has been prepared in accordance with the requirements of Article 31 of EU Regulation 1907/2006 (as amended) on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Independence Medical Barrier Film Wipes
SYNONYMS: Fluid in Tissues
PRODUCT CODES: BW1
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: 1 800 262 8200 (USA only)
FAX PHONE: +44 (0) 208 944 5434
CHEMICAL NAME: Hexamethyldisiloxane
Thermobonded Non-Woven
PRODUCT USE: This product is used to remove any residual adhesive left on the skin when removing Non Invasive Urology/Ostomy Bags or Similar Appliances that use Medical Adhesives
PREPARED BY: ProSys International Ltd

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT	CAS NUMBER	EINECS NUMBER	Risk Classification
Hexamethyldisiloxane	107-46-0	203-492-7	H225 (Highly Flammable) H400 (Very toxic to aquatic organisms)
Octamethyltrisiloxane	107-51-7	-	-
Decamethylcyclopentasiloxane	541-02-6	-	-
Tetra (trimethylsiloxy)silane	3555-47-3	-	-
Polypropylene Fibres	9003-07-0	204-062-1	-

SECTION 3: HAZARDS IDENTIFICATION

The principal hazards of the product as supplied are:

Highly flammable.

Very toxic to aquatic organisms.
Vapours may form explosive mixtures with air.

Accidental thermal decomposition or melting state can present hazards.

EYES: Direct contact may cause mild irritation

SKIN: No significant irritation expected

INHALATION: Irritates respiratory passages very slightly. Vapour exposure may cause drowsiness

INGESTION: Swallowing large amounts may cause drowsiness (for liquid state only)

SECTION 4: FIRST AID MEASURES

POTENTIAL HEALTH EFFECTS

EYES: Irrigate thoroughly with luke warm water for 15 minutes. Seek medical advice if irritation persists.

SKIN: No Health effects are expected however if redness/irritation occurs advise wash skin with soap & water for 5 minutes

INGESTION: If ingested, seek medical advice if significant quantities have been swallowed.

INHALATION: Remove Patient to fresh air.

NOTE: Users that have a history of skin allergies should receive medical advice should irritation occur. Note to medical team, treat according to persons condition & specific of exposure.

SECTION 5: FIRE FIGHTING MEASURES

Extinguishing media: On large fires use alcohol compatible foam or water spray (fog). On small fires use alcohol compatible foam, CO₂ or water spray (fog). Water can be used to cool fire exposed containers.

Unsuitable extinguishing media: No water near electrical devices

Hazards during fire-fighting: Fire burns more vigorously than would be expected. Vapours are heavier than air and can travel along ground to remote ignition sources. Electrostatic charges may be generated during transfer of product from its container. Ensure that all equipment is electrically earthed. Vapours may form explosive mixtures with air.

Special protective equipment:	For large fires, a self-contained respirator and protective clothing should be worn. Determine the need to evacuate or isolate the area according to your local emergency plan. Use water spray to keep fire exposed containers cool.
Hazardous Combustion Products:	Thermal breakdown of this product during fire or very high heat conditions may evolve the following decomposition products: Silica. Carbon oxides and traces of incompletely burned carbon compounds. Formaldehyde

SECTION 6: ACCIDENTAL RELEASE MEASURES

Note:	These measures are applicable to the ingredients in its raw sub-state only
Accidental Release Measures:	Wear proper protective equipment.
Precautions to protect the environment:	Do not empty into drains. Prevent from spreading or entering into drains, ditches or rivers by using sand, earth or other appropriate barriers. Inform Local Authorities if this cannot be prevented.
Methods for cleaning up:	Determine the need to evacuate or isolate the area according to your local emergency plan. Eliminate all possible sources of ignition. For very large spills these should be contained by bunding, etc. procedures. Mop, wipe or soak up with absorbent material and place in a container with a lid. The spilled product produces an extremely slippery surface

SECTION 7: HANDLING & STORAGE

Advice on safe handling:	Read the label before use. General ventilation is required. Local ventilation is recommended. Do not breathe vapour. Do not breathe spray or mist. Avoid eye contact. Do not mix with other chemicals. Keep out of reach of children Dust from the Polypropylene Fibres is not expected in its prepared state.
Advice on storage:	Store in a flameproof, well ventilated area. Electrostatic charges may be generated during transfer of product from its container. Ensure that

all equipment is electrically earthed. Keep container tightly closed.

Vapours may form explosive mixtures with air. Store at ambient temperatures under dry conditions

Specific uses: Refer to technical data sheet available on request.

Unsuitable packaging materials: Not known

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Ventilation - Refer to Section 7. Do not smoke during use

Exposure controls for hazardous components

Name	Exposure Limits
Hexamethyldisiloxane	200 ppm (8h TWA) Dow Corning recommendation
Octamethyltrisiloxane	TWA 200 ppm
Decamethylcyclopentasiloxane	TWA 10 ppm
Polypropylene Fibres	ggw.6mg/cbn

Personal protection equipment

Respiratory protection: Do not breathe in spray. For bulk product - Suitable respiratory protection should be worn if the product is used in large quantities, confined spaces or in other circumstances where the OEL may be approached or exceeded. A suitable respirator must be worn if the product is used in any circumstances where an aerosol or mist may be generated, such as during spraying or similar activities. Depending on the working conditions, wear a respiratory mask with filter(s) AP or use a self-contained respirator. The choice of a filter type depends on the amount and type of chemical being handled in the workplace. Regarding filter characteristics, contact your respiratory protection supplier.

Hand protection: For bulk product – Select gloves which are appropriate to protect contact with skin.

Eye protection: For bulk product - Safety glasses should be worn.

Skin protection: For bulk product - Protective equipment is not normally necessary.

Hygiene measures: Exercise good industrial hygiene practice. Wash after handling, especially before eating, drinking or smoking.

Environmental exposure controls: Refer to section 6 and 12.

Additional information: These precautions are for room temperature handling. Use at elevated temperature or aerosol/spray applications may require added precautions. For further information regarding the use of silicones/organic oils in consumer aerosol applications, please refer to the guidance document regarding the use of these types of materials in consumer aerosol applications that has been developed by the silicone industry (www.SEHSC.com) or contact the Dow Corning customer service group.

SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

Form: Liquid in Textile Fabric

Colour: White

Odour: Characteristic odour

Important health, safety and environmental information

Boiling point/range: 100 °C

Melting point/range: -68 °C to 163°C

Flash point: Less than 0° typically -3.3 °C (Pensky-Martens Closed Cup)

Lower flammable limits: 1.50 %

Upper flammable limits: Lower Limit 1.50% Upper Limit 14.65 %

Autoignition temperature: 352 °C

Explosive properties: No

Vapours may form explosive mixtures with air.

Vapour pressure: 4.2 kPa at 20°C.

Specific Gravity range: 0.76 to 1.050 at 25°C

Partition coefficient (Log n-octanol/water): 4.76

Viscosity:	0.65 mm ² /s at 25°C.
VOC content:	760 g/l
Molecular weight:	162
Oxidizing properties:	No

SECTION 10: STABILITY AND REACTIVITY

STABILITY:	Stable & unreactive
CONDITIONS TO AVOID (STABILITY):	Sources of Ignition
INCOMPATIBILITY (MATERIAL TO AVOID):	Oxidising Acids/Materials; Open Flame
HAZARDOUS DECOMPOSITION:	May emit Flammable Gases; Carbon Oxides; Carbon Monoxide; Carbon Dioxide; Silicon Dioxide; and fine particulates in the form of smoke. Formaldehyde (See Section 5)
HAZARDOUS POLYMERIZATION:	Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

On contact with eyes:	May cause temporary discomfort.
On skin contact:	No adverse effects are normally expected.
If inhaled:	No adverse effects are normally expected in humans, however toxic fumes if ignited
On ingestion:	No adverse effects are normally expected. Deliberate inhalation abuse could prove fatal in extreme circumstances.
Other Health Hazard Information:	Product may emit formaldehyde vapour at temperatures above 150°C in the presence of air. Formaldehyde vapour is a suspected carcinogen, toxic by inhalation and

irritating to eyes and the respiratory system. Exposure limits should be strictly respected

Acute Toxicity: Tests on Rats LC50 over a two year period observed an increase in Leydig Cell Tumours; Uterine Endometrial Tumours; and Kidney Tumours, however there was lack of evidence that it had any relevance to humans

SECTION 12: ECOLOGICAL INFORMATION

Environmental fate and distribution

Low molecular weight volatile siloxanes have very low water solubility and evaporate to air. Low molecular weight volatile siloxanes in air are degraded by reaction with hydroxyl radicals, which is the dominant degradation process for most chemicals in the atmosphere. Low molecular weight volatile siloxanes in soil are removed by several simultaneously occurring processes including volatilisation, hydrolysis, and clay-catalysed degradation.

This product hydrolyses in water, releasing silanols. Hexamethyldisiloxane degrades in the atmosphere and does not persist in soil or water.

Eco-toxicity effects

Very toxic to aquatic organisms.

Fish: Oncorhynchus mykiss 96 Hrs LC50 0.46 mg/L

Invertebrates: Daphnia magna 72 Hrs EC50 0.79 mg/L

Algae: Selenastrum capricornutum 96 Hrs EC50 > 0.93mg/L

Bioaccumulation: Low molecular weight volatile siloxanes bioconcentrate in fish exposed under controlled laboratory conditions that are not representative of conditions found in the environment.

Fate and effects in waste water treatment plants

No adverse effects on bacteria are predicted. The siloxanes in this product do not contribute to the BOD. Low molecular weight volatile siloxanes are efficiently removed (>90%) during wastewater treatment with approximately equal amounts going to the atmosphere and the sludge. Low molecular weight volatile siloxanes in treated wastewater effluent will be bound to particulate matter because of very low water solubility.

SECTION 13: DISPOSAL CONSIDERATIONS

Product disposal: This material must be disposed of as hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not puncture or incinerate even when empty.

Packaging disposal: Dispose of in accordance with local regulations. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

SECTION 14: TRANSPORT INFORMATION

Road / Rail (ADR/RID)

UN No.: UN 1993

Proper Shipping Name: FLAMMABLE LIQUID

Class: 3 (C)

Packing group: II1 (3)

Labels: 3

Sea Transport (IMDG)

UN No.: UN 1993 & UN Code 1950

Proper Shipping Name: FLAMMABLE LIQUID

Class: 3

Packing group: II1 (3)

**Emergency Schedule:
(Ems)** F-E
S-E

Labels: flammable liquid

Air transport (IATA)

UN No.: UN 1993

Proper Shipping Name: Flammable liquid

Class: 3

Packing group: II1 (3)

Labels: Flammable Liquid

SECTION 15: REGULATORY INFORMATION

As follows:

This material has been classified according to the requirements of implementing the United Nations “Globally Harmonised System of Classification and Labelling of Chemicals” (GHS), EU Regulation 1271/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (the CLP Regulation)

Product Label

Extremely Flammable

Safety Phrases

P102 Keep out of the reach of children

P210 Keep away from heat/sparks/open flames/hot surfaces – NO SMOKING

P273 Avoid release to the environment

P381 Eliminate all sources of ignition if safe to do so

Hazard Pictograms



Highly Flammable

Hazardous to the Environment

MEDICAL DEVICES DIRECTIVE 93/42/EC:

Compliant

EU REACH REGULATIONS:

Compliant

EU SUBSTANCES OF VERY HIGH CONCERN (SVHC):

Compliant

OZONE DEPLETING CHEMICALS:

No ozone depleting chemicals are present or used in manufacture.

EINECS:

All ingredients listed or exempt.

TSCA:

All chemical substances in this material are included on or exempted from listing on the TSCA Inventory of Chemical Substances.

SECTION 16: OTHER INFORMATION

HISTORY:

Version 1. Dated 7th June 2017

DISCLAIMER:

The information contained within this MSDS is based only upon our current level of knowledge.

This information is given for guidance only and is not to be considered as a warranty

REGULATIONS:

This Product complies with the Medical Device Directive 93/42/EC and is categorised as Class 1

PREPARED BY:

ProSys International Ltd

END