

# MATERIAL SAFETY DATA SHEET

## Independence Medical Adhesive Remover Wipes

Technical File: TF18

Product Code: ARW1



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 Adhesive Remover Wipes
SYNONYMS:	Fluid in Tissues
PRODUCT CODES:	ARW1
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)
Polypropylene Fibres	9003-07-0	204-062-1	-

### SECTION 3: HAZARDS IDENTIFICATION

**IMMEDIATE HEALTH HAZARDS:** This product when used under reasonable conditions and in accordance with the ProSys Instructions for Use, should not present a health hazard. However, use or processing of this product in a manner not in accordance with the Instructions for Use, may affect the performance of the product and may present potential health & safety hazards.

Highly flammable.

**IN LIQUID BULK FORM:** Note: Not applicable to ARW1

<b>EYE:</b>	May cause eye irritation.
<b>SKIN:</b>	May cause skin irritation.
<b>INGESTION:</b>	May cause irritation of the digestive tract.
<b>INHALATION:</b>	May cause respiratory tract irritation.

## SECTION 4: FIRST AID MEASURES

<b>EYES:</b>	Irrigate thoroughly with water. Seek medical advice if irritation persists.
<b>SKIN:</b>	No Health effects are expected however if redness/irritation occurs wash skin with soap & water.
<b>INGESTION:</b>	If ingested, seek medical advice if significant quantities have been swallowed.
<b>INHALATION:</b>	For bulk liquids only - remove patient to fresh air.
<b>NOTE:</b>	Users that have a history of skin allergies should receive medical advice if irritation occurs.
<b>PROTECTION OF FIRST AIDERS:</b>	Not applicable

## SECTION 5: FIRE FIGHTING MEASURES

<b>Extinguishing media:</b>	On large fires use alcohol compatible foam or water spray (fog). On small fires use alcohol compatible foam, CO <sub>2</sub> (Carbon Dioxide) or water spray (fog). Water can be used to cool fire exposed containers. Dry Chemicals may also be used.
<b>Unsuitable extinguishing media:</b>	No water near electrical devices.
<b>Hazards during fire-fighting:</b>	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.
<b>Special protective equipment:</b>	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.
<b>Hazardous Combustion Products:</b>	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

Finished Products (ARW1) used in the home may be disposed of within the household waste system. Products used in a care facility, should ideally be disposed of in the clinical waste system. Always check with your local regulatory authority.

These measures are applicable to the Hexamethyldisiloxane in its raw sub-state (bulk liquid) only.

**Accidental Release Measures:** Wear proper protective equipment.

**Spills/Leaks:** Absorb spill with inert material (e.g. vermiculite, sand or earth), then place in suitable container. Remove all sources of ignition. Use a spark-proof tool. Do not let this substance enter the environment. For example: Do not empty into drains. Prevent from spreading or entering into storm water drains, ditches or rivers by, using sand, earth or other appropriate barriers. Inform Local Authorities if this cannot be prevented.

## SECTION 7: HANDLING & STORAGE

Store in customary room temperature (ambient) and humidity conditions.

Do not use after the indicated expiration date or if the packaging has been damaged.

**Handling:** For bulk materials, use spark-proof tools and explosion proof equipment. Do not get in eyes, on skin, or on clothing. Keep away from heat, sparks and flame. Do not ingest or inhale.

**Storage:** Keep away from sources of ignition. Store in a cool, dry place. Store in a tightly closed container. Keep out of direct sun light.

**Note:** For bulk liquids, which is not applicable to ARW1, store in a flameproof, well ventilated area.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

No personal protection is needed to handle Independence Adhesive Remover Wipes.

The device does not produce powders or dust under normal use.

**ENGINEERING CONTROLS:** Not applicable to a finished product.

**RESPIRATORY PROTECTION:** Not applicable to a finished product. For bulk liquid - A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 must be followed whenever workplace conditions warrant respirator use.

<b>HAND PROTECTION:</b>	Not applicable to a finished product. For bulk liquid - gloves are not normally required.
<b>EYE PROTECTION:</b>	Not applicable to a finished product. For bulk liquid - Safety glasses should be worn.
<b>SKIN PROTECTION:</b>	During use by the patient - in the event of an allergic reaction or skin irritation, cease use and seek the advice from a care professional. For bulk liquid - Wear appropriate protective gloves to prevent skin exposure
<b>EXPOSURE GUIDELINES:</b>	None established.

## SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

<b>Form:</b> Liquid in Textile Fabric	<b>Colour:</b> White	<b>Odour:</b> Characteristic odour
Boiling point/range:	100 °C	
Melting point/range:	-68 °C	
Flash point:	Less than 0° typically -3.3 °C (Pensky-Martens Closed Cup)	
Lower flammable limits:	1.50 %	
Upper flammable limits:	14.65 %	
Autoignition temperature:	352 °C	
Vapour pressure:	4.2 kPa at 20°C.	
Specific Gravity:	0.76	
Partition coefficient (Log n-octanol/water):	4.76	
Viscosity:	0.65 mm <sup>2</sup> /s at 25°C.	
VOC content:	760 g/l	
Molecular weight:	162	
Oxidizing properties:	No	

## SECTION 10: STABILITY AND REACTIVITY

<b>STABILITY:</b>	Stable and unreactive
<b>CONDITIONS TO AVOID:</b>	Sources of Ignition
<b>INCOMPATIBILITY:</b>	Oxidising Acids; Open Flame
<b>HAZARDOUS DECOMPOSITION:</b>	May emit Carbon Monoxide; Carbon Dioxide; and fine particulates in the form of smoke. Formaldehyde.
<b>HAZARDOUS POLYMERIZATION:</b>	Will not occur

## SECTION 11: TOXICOLOGICAL INFORMATION

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

This 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.

As at the date of this publication, the components contained in Independence Medical Adhesive Remover Wipes are not listed on the EU Candidate List of Substances of Very High Concern (SVHC) according to the REACH Regulations.

Mutagenicity:	No information found
Neurotoxicity:	No information found
Teratogenicity:	No information found
Carcinogenicity:	CAS 107-46-0 & CAS 9003-07-0 - Not listed by ACGIH, IARC, NTP, or CA Prop 65.

## SECTION 12: ECOLOGICAL INFORMATION

<b>Eco-toxicity effects:</b>	Very toxic to aquatic organisms.
<b>Environmental fate and distribution:</b>	Hexamethyldisiloxane degrades in the atmosphere and does not persist in soil or water.
<b>Fate and effects in waste water treatment plants:</b>	No adverse effects on bacteria are predicted

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>ENT/USER:</b>	Dispose of any used, damaged or out of date Independence Medical Adhesive Remover Wipes.
<b>RIBUTOR/WAREHOUSE:</b>	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.

## SECTION 14: TRANSPORT INFORMATION

<b>Road / Rail (ADR/RID)</b>	
<b>UN No.:</b>	UN 1993
<b>Proper Shipping Name:</b>	FLAMMABLE LIQUID, N.O.S. (Hexamethyldisiloxane)
<b>Class:</b>	3
<b>Packing group:</b>	II
<b>Labels:</b>	3

**Sea Transport (IMDG)**

**UN No.:** UN 1993 & UN Code 1950  
**Proper Shipping Name:** FLAMMABLE LIQUID, N.O.S.(Hexamethyldisiloxane)  
**Class:** 3  
**Packing group:** II  
**Emergency Schedule:** F-E  
**(Ems)** S-E  
**Labels:** Flammable liquid

**Air transport (IATA)**

**UN No.:** UN 1993  
**Proper Shipping Name:** Flammable liquid, n.o.s. (Hexamethyldisiloxane)  
**Class:** 3  
**Packing group:** II  
**Labels:** Flammable Liquid

**SECTION 15: REGULATORY INFORMATION**

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

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:** 7th June 2017.

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