

MATERIAL SAFETY DATA SHEET

Independence Extra Sticky Wound Protection/Collection Pouch

Technical File: TF36

Product Code: EA2



SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	Independence Extra Sticky Wound Protection/Collection Pouch
SYNONYMS:	Stoma Pouch
PRODUCT CODES:	EA2
MANUFACTURER:	ProSys International Ltd
DIVISION:	Regulatory Affairs - London
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CHEMICAL NAME:	Thermoplastic Polymer & Ethylene vinyl acetate
PRODUCT USE:	These pouches are intended for activity use, such as showering, bathing, swimming, or for short periods when dry protection and comfort is required
PREPARED BY:	ProSys International Ltd

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	C.A.S. No.	% by Wt
Wafer		
Liner	Unknown	40 - 60
Polyethylene foam	9002-88-4	20 - 40
Acrylic adhesive	Trade Secret	10 - 20
Pouch		
Ethylene vinyl acetate (EVA)	24937-78-8	100

SECTION 3: HAZARDS IDENTIFICATION

Wafer

Specific Physical Form:	Roll of Tape
Odor, Color, Grade:	Tan foam tape with slight acrylic odour.
General Physical Form:	Solid

Immediate health, physical, and environmental hazards: This product, when used under reasonable conditions and in accordance with the ProSys International Ltd's instructions for use, should not present a health hazard. However, use or processing of the product in a manner not in accordance with the product's directions for use may affect the performance of the product and may present potential health and safety hazards.

Pouch

EVA films do not present any significant hazard to health and safety when used for their intended purposes in accordance with practices in hygiene and good housekeeping.

EVA films can form vapours or fumes when heated to more than 235°C which may cause irritation of respiratory tract and cause coughing and sensation of shortness of breath.

Skin contact with “hot” EVA films may cause severe thermal burns.

EVA films are combustible if exposed to flames.

EVA film can accumulate static electrical charges. The rapid leaking of such charges to earth in the form of sparks is potentially dangerous in areas where flame or explosion hazards exist.

General Hazard Statements**Eye Contact:**

No health effects are expected.

Skin Contact:

No health effects are expected.

Inhalation:

No health effects are expected.

Ingestion:

Physical Blockage: Signs/symptoms may include cramping, abdominal pain, and constipation.

SECTION 4: FIRST AID MEASURES

The following first aid recommendations are based on an assumption that appropriate personal and industrial hygiene practices are followed.

Eye Contact: No need for first aid is anticipated.

Skin Contact: No need for first aid is anticipated.

Inhalation: No need for first aid is anticipated.

If Swallowed: Do not induce vomiting unless instructed to do so by medical personnel. Give victim two glasses of water. Never give anything by mouth to an unconscious person. Get medical attention.

Additional first aid measures are required when the Polyethylene foam and/or EVA are in their liquid foam. This is not anticipated for the EA2 medical device which is supplied to the market as a finished article.

SECTION 5: FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES

Autoignition temperature:	No Data Available
Flash Point:	Not Applicable
Flammable Limits(LEL):	Not Applicable
Flammable Limits(UEL):	Not Applicable

EXTINGUISHING MEDIA

Ordinary combustible material. Use fire extinguishers with class A extinguishing agents (e.g. water, foam). Use fire extinguishers with class B extinguishing agents (e.g. dry chemical, carbon dioxide).

Do not use water/water sprays near electrical equipment.

PROTECTION OF FIRE FIGHTERS

Special Fire Fighting Procedures: Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA). For bulk material, burning devices should not be approached without the use of positive pressure self-contained breathing apparatus and helmet with face shield.

Unusual Fire and Explosion Hazards: Not applicable.

Note: See STABILITY AND REACTIVITY (SECTION 10) for hazardous combustion and thermal decomposition information.

Note: In burning situations, carbon monoxide, acrolein and other toxic aldehydes may be present together with a thick dense smoke

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Not applicable.

Environmental precautions

Not applicable.

Clean-up methods

Not applicable in its finished state.

Note: In its liquid form, the raw materials (ingredients) presents a potential slip or trip hazard and should be cleaned up immediately. The preferred methods of cleaning are sweeping or picking up. The discarded material should be disposed of according to local disposal regulations.

SECTION 7: HANDLING & STORAGE

HANDLING

This product is considered to be an article which does not release or otherwise result in exposure to a hazardous chemical under normal use conditions.

When handling bulk material, use the appropriate lifting equipment.

STORAGE

Not to be stored in direct sun light. Keep dry. Do not use if packaging is damaged

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS

For its liquid state - Good general ventilation of workshops is essential to minimise the concentration of fumes. Local exhaust ventilation is strongly recommended to reduce fumes where the film is being sealed.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Eye/Face Protection

Not applicable. However face shields or safety glasses must be worn when handling molten material.

Skin Protection

The polymer selected do not normally cause skin irritation. Any such problems can usually be eliminated by the use of barrier creams. Gloves or other suitable protective clothing must be worn if handling molten film.

Respiratory Protection

Not applicable as a finished article. For its molten state, contact ProSys International Ltd for additional information.

Prevention of Swallowing

Not applicable.

EXPOSURE GUIDELINES

None Established

SECTION 9: PHYSICAL & CHEMICAL PROPERTIES

Specific Physical Form:	Traditional Stoma Pouch
Odour, Color, Grade:	Tan foam tape & clear (colourless) pouch with slight acrylic odour.
General Physical Form:	Solid
Auto ignition temperature:	360° centigrade
Flash Point:	380° centigrade
Flammable Limits(LEL):	Not Applicable
Flammable Limits(UEL):	Not Applicable
Boiling Point:	Not Applicable
Vapor Density:	Not Applicable
Vapor Pressure:	Not Applicable
Specific Gravity:	Not Applicable
pH:	Not Applicable
Melting point:	80° – 110° centigrade
Solubility in Water:	Insoluble
Evaporation rate:	Not Applicable

Volatile Organic Compounds:	Prolonged immersion in aromatic hydrocarbons and/or n-paraffins can cause swelling at room temperatures and dissolving at higher temperatures.
Kow - Oct/Water partition coef:	No Data Available
VOC Less H2O & Exempt Solvents:	No Data Available
Viscosity:	Not Applicable

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability:	Stable. Films (Pouches) are stable under normal handling and storage conditions. If stored continuously in direct sunlight photo degradation occurs and the storage time under these conditions reduces to less than 1 month
Conditions to avoid:	None known
Materials to avoid:	None known
Hazardous Polymerization:	Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

SECTION 11: TOXICOLOGICAL INFORMATION

In Vitro Cytotoxicity (Agar Overlay)

Protocol reference: Guess, W. L. et al; "Agar Diffusion Method for Toxicity Screening of Plastics on Cultured Cell Monolayers" J. Pharm. Sci. 54:1545-1547 (1965).

Results : 0.0/0.0

Repeat Skin Irritation in Albino Rabbits

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.

Results : 0.0/8.0

Repeated Insult Patch Test (Draize) in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.

Results : No allergic contact dermatitis or untoward effects observed.

21-day Cumulative Irritation in Humans

Protocol reference: Draize: Appraisal of the Safety of Chemicals in Food, Drugs and Cosmetics (1965). Published by the Editorial Committee of the Association of Food and Drug Officials of the United States.

Results : Results were consistent with responses characteristic of adhesive materials; no untoward effects.

In addition, the foam alone has been subjected to the following tests:

Primary Skin Irritation Test (FHSA) – non irritating

Ocular Irritation Study (USP/NF) – no evidence of significant eye irritation

Cytotoxicity- Agarose Overlay, Solid – non-cytotoxic

These tests are in accordance with the ISO 10993 Part-1 "Biological Evaluation of Medical Devices", as put forth by the FDA. The adhesive used with No. 9776 has satisfied the requirements for devices in contact with intact skin for short-term application (up to 29 days). All laboratory testing was conducted in accordance with the FDA Good Laboratory Practices Regulation of 1978.

The use of the term "hypoallergenic" has come to indicate a product that is non-sensitizing to the general public. The hypoallergenic claim for this product is supported by clinical evaluation using the repeated insult patch test in humans, commonly known as the Draize test. This protocol involves repeated application of samples on 200 healthy volunteers for a 2- to 3-week induction period, followed by a 2-week rest period and a challenge application. To be termed hypoallergenic, ProSys Medical Specialties products are required to show no evidence of sensitization potential under these test conditions.

Ingestion - The toxicity from ingestion of the polymers used is minimal; however some breathing difficulties or choking may occur if swallowed in its liquid state.

Eye Contact - Particulates of the raw materials (not finished articles) may cause mechanical irritation to the eyes.

Skin Contact - Cured films are generally not absorbed by the skin and are essentially non-irritating. If irritation occurs use barrier cream. At elevated temperatures thermal burns to the skin may occur.

Inhalation - Films used for the pouches do not create vapours below 30° C therefore are safe for their intended use. At elevated temperatures some irritating vapours may be given off. The use of local exhaust ventilation is strongly recommended.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION

Not applicable.

CHEMICAL FATE INFORMATION

Not applicable.

Note: Films are insoluble in water and do not present itself as an aquatic hazard. The material is non-biodegradable and can remain unaffected for years in a landfill site.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal Method: Dispose of waste product in a sanitary landfill. As a disposal alternative, incinerate in an industrial or commercial facility in the presence of a combustible material.

Recycling: EVA films (uncontaminated pouches) can be reprocessed by recycling companies. Polyethylene (uncontaminated wafer) can be granulated by specialist recycling companies.

EPA Hazardous Waste Number (RCRA): Not regulated

EUROPEAN WASTE CODE: 18.01.04

Note: As regulations on both recycling and disposal vary, consult applicable regulations from the authorities before disposal.

SECTION 14: TRANSPORT INFORMATION

Wafer - ID Number(s):

70-0000-6358-9, 70-2006-7582-8, 70-2007-7626-1

Pouches

EVA film is not classified according to any recommendations relating to the transport of dangerous goods.

SECTION 15: REGULATORY INFORMATION

CHEMICAL INVENTORIES

This product is an article as defined by TSCA regulations, and is exempt from TSCA Inventory listing requirements.

MEDICAL DEVICES DIRECTIVE 92/43/EEC

Compliant

CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH REGULATIONS 2004

Compliant

REGISTRATION, EVALUATION, AUTHORIZATION & RESTRICTION OF CHEMICALS REGULATIONS 1907/2006

Compliant

SECTION 16: OTHER INFORMATION

HISTORY:

Version 1. Dated 16th February 2018

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

PREPARED BY:

ProSys International Ltd