

# ADHESIVE ISLAND DRESSINGS WITH EXPANDING PAD

## MATERIAL SAFETY DATA SHEET

**Product name:** Adhesive island dressings with expanding pad.

**Ref. Nos.** of Adhesive island dressings with expanding pad: **00450 - 00499**

**Product and Company Identification:**

**Product names:** DIAPRES™, I.V. Eur-A-Fix, I.V. cannula dressing, adhesive island dressings with expanding pad.

**Intended Use:**

1. Hemostat dressing.
2. To cover bleeding/exuding wounds and absorb fluids.
3. To cover needle exit site.
4. To secure I.V. cannula and cover needle exit site.
5. To cover and protect wounds.

**Supplier: Manufacturer:**

Pollak (International) Ltd. **EUROBAND**

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**Indications**

DIAPRES™: To cover needle exit sites during and after dialysis (hemostat).

I.V. Eur-A-Fix™: To secure I.V. cannula and cover needle exit sites while absorbing blood spurts, haemostatic.

I.V. Eur-A-Fix™ Flesh Color: To secure I.V. cannula and cover needle exit sites, using water repellent backing substrates, while absorbing blood spurts at needle Exit Site, haemostatic.

I.V. Eur-A-Fix™ Transparent: To secure I.V. cannula and cover needle exit sites, using transparent waterproof backing substrates, while absorbing blood spurts at needle Exit Site, haemostatic.

**Composition/Information on Ingredients:**

Material	Ingredients/Construction	Characteristics
Expanding Pad 305gr/m <sup>2</sup> ±10% Absorbency g/g 77.4 pH 6,5	PP Water-proof layer Viscose fibers - 50% mingled with Supper Absorbent (Polyacrylate) Fibers - 50% Non absorbent 12 µ polyethylene net	Non-Adherent, Absorbs, Expands & turns to solid gel.
Backing material White Eur-A-Fix	Polyamide 70% Viscose 20% Polyester 10% Highly porous thermally bonded uniform structure	Elastic, Highly Porous Air Permeable
Backing Material Flesh Color Eur-A-Fix	Polyamide filaments 100%, Acrylic binder bonded Hydrophobic treatment	Elastic, Highly Air Permeable
Backing Material transparent Eur-A-Fix	Polyurethane film 12 µ	Transparent low air permeability.
Adhesive	Acrylic Hypo Allergenic Adhesive Coated in Strips	

**Properties:**

Adhesive backing cut into various shapes; "rectangular", "H", "round" all with rounded corners. Centrally placed expanding dressing pad that absorbs and expands on contact with fluids.

**Hazards Identification:**

**Emergency Overview: N.A**

**Contraindication:**

Known cases of sensitivity to Hypo Allergenic Acrylic adhesives.

Do not use if pack is damaged or open.

I.V. Eur-A-Fix Transparent; should be replaced every 24 hours at most.

**Signs and Symptoms of Overexposure** - N.A

**First Aid Measures**

Remove the adhesive tape.  
Clean skin with medical solvents used to clean adhesive residues.

**Fire Fighting Measures** – N.A

**Autoignition temperature:** N.A.

**Hazardous Combustion Products:** - N.A

**Accidental Release Measures:**

Material is compressed to solid, no spillage measures are required.  
**Caution:** while removing the silicon cover, do not touch the expanding pad to avoid contamination.

**Handling and Storage:**

Individual pack of Island Dressing should be stored in its original carton.  
Prior to use, peel apart the pouch pack and expose the island dressing in aseptic manner; remove first silicon paper, place the island dressing centered over the exit site, and adhere the adhesive material to skin. Remove the other silicon paper/papers keeping the adhesive tape stretched – adhere the exposed adhesive.  
**Storage Precautions:** Store in cool, dry place avoid extreme light.

**Exposure Control/Personal Protection**

Engineering Controls: General exhaust is adequate  
Eyes: None necessary under normal conditions of use.  
Respirator: None necessary under normal conditions of use.  
Skin: None necessary under normal conditions of use.  
Other: None necessary under normal conditions of use.  
Work/Hygienic Practices: Practice good personal hygiene.

**SHELF LIFE**

Following sterilization the product has five (5) years shelf life, provided that it is stored in the original packaging in recommended storage condition and that the packs are not damaged or opened or tampered with in any way.

**STERILIZATION INFORMATION**

Sterilized by ETO (Ethylene Oxide 20% and Carbon Dioxide CO<sub>2</sub> 80%)  
ETO sterilization is conducted according to ISO –11135 standards and has been validated and approved by the USA FDA and our CE Competent Authority.  
**Microbial Tests:** according to USP 24, page 1816.  
**Results:** Products were found sterile.

**Stability and Reactivity**

**General:** Stable.  
**Incompatible Materials:** Strong Oxidizing Agents.  
**Conditions to Avoid:** Exposure to excessive Heat or cold.  
**Hazardous Decomposition/Hazardous Combustion:** N.A  
**Hazardous Polymerization:** In temperature exceeding 40°C

**BIOCOMPATIBILITY TESTS**

Biocompatibility Tests: conducted according to the relevant paragraphs in USP 24, page 861 – “ Absorbent Gauze” - replacing “gauze” by “Island Dressing”.

The results were in the requested limits, as follows:

Acid/Alkali	Neutral (>6,5 <7)
Absorption per second (Expanding Pad)	2 sec.
Water extract	0.8%
Starch – Dextrin	none
Ether Soluble substances	0.21%
Water holding capacity of own weight (Expanding Pad)	g/g 77.4 Average
Surface active substances	OK

**Physical and Chemical Properties****Appearance:** Smooth cut edges with no lint.**Vapor Pressure:** N.A.**Solubility in Water:** NO**Melting point:** N.E.**Boiling Point:** N.A.**Odor:** No discernable odor**Vapor Density:** N.A.**Specific Gravity:** N.E.**Percent Volatility (by wt):** N.A.**Toxicological Information of the Expanding Material:**

- I. **Acute oral toxicity in mice:** LD50>5,000 mg/kg
- II. **Rabbit Skin Irritation:** No clinical signs indicative of irritation.
- III. **Human Skin Patch Test:**  
The results of the skin irritation and skin sensitization with pieces of Lanseal F Non-woven cloth put on human skin (24 hour patch on 20 persons) are shown below:  
Microscopically judgement  
Stimulation B (Deep Furrows): Almost negative (Index I.B)  
Stimulation C Irregular ridges and furrows, lamellar: Negative (Index O.C)  
Scales and creased ridges)  
Macroscopically judgement  
Stimulation D (Erythema, edema and papule) : Negative (Index O.D)
- IV. **“Femine Care Products Standards: from the Notice no. 285 by the Ministry of Health and Welfare 1966 (JAPAN)**
- | <u>Item</u>     | <u>Test result</u> |
|-----------------|--------------------|
| Acid and alkali | No indication      |
| Coloring matter | No indication      |
| Fluorescence    | No observation     |
| Ash content     | 0.47%              |
- V. **“Packing of plastic implement and container” from the Notice No. 434 by the Ministry of Health and Welfare 1966 (JAPAN)**
- | <u>Item</u>                        | <u>Test Result</u> |
|------------------------------------|--------------------|
| Phenol                             | No detection       |
| Formaldehyde                       | No detection       |
| Heavy metal                        | No detection       |
| Potassium permanganate consumption | 10 PPM or below    |
- VI. **Biological decomposition:-** Lanseal F does not decompose by microorganisms
- VII. **Ammonia absorption capacity:** About 30% of carboxyl group (COO<sup>-</sup>) of Lanseal F exist in the form of -COOH, which reacts with NH<sub>3</sub> as follows:  
-VOOH + NH<sub>3</sub> → . COO NH<sub>4</sub>  
Consequently, NH<sub>3</sub> is absorbed into Lanseal F. This property contributes to Deodorization of the smell of ammonia and prevention of skin roughening especially in the uses of sanitary goods.  
About 0.015 g of ammonia is absorbed b one gram of Lanseal F at the maximum.
- VIII. **Ames mutagenesis test :** Salmonella typhimurium TA98 & TA 100: Negative
- IX. **Primary Ocular irritation test on rabbits described by FDA**  
No ocular irritation effect was observed
- X. **Dermal sensitization test on guinea pigs, according to maximization procedure**  
Lanseal ZF exhibited no dermal sensitization, and was evaluated as negative sensitizer.
- XI. **Formaldehyde, (method: SFS 4996 (ppm) <10**

**Ecological Information:**

N.E

**Disposal Considerations:**

Dispose or incinerate in accordance with all applicable regulations for disposal of medical products.

**Transportation Information:**

No specific requirements to be met; not regulated as a hazardous material. Avoid exposure to temperature below 1<sup>0</sup>C and over 40<sup>0</sup>C

**Regulatory Information:**

**USA – FDA = Class I device**

**CE =Class I sterile device**

**Other Information:**

Legend: N.A= not applicable N.E = Not Established N.D = Not Determined

Approved by:

**POLLAK (INTERNATIONAL) LTD – Quality Assurance**

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