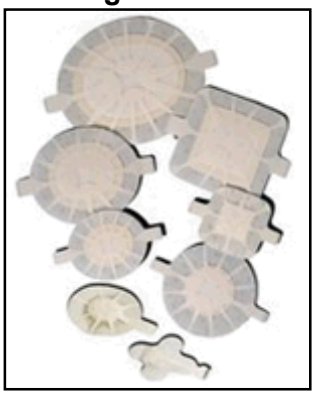
**3M™ Tegaderm™ Foam Adhesive; High Performance Foam Adhesive Dressing &**

**3M™ Tegaderm™ Foam Adhesive Dressing With Soft Cloth Border**



## General Description

### 3M™ Tegaderm™ Foam Adhesive; High Performance Foam Adhesive Dressing 90610, 90611, 90612, 90613, 90614, 90616, 90619, 90616D, 90619D

3M™ Tegaderm™ High Performance Foam Adhesive Dressing is a “moisture-reactive” absorbent, breathable wound dressing. It is constructed from 4 different layers: a conformable polyurethane foam pad, 2 additional absorbent nonwoven layers, and a top layer of transparent adhesive film. This film is moisture vapor permeable. It prevents wound exudate strike-through and acts as a barrier to outside contamination, including bacterial and viruses.* As a “moisture-reactive” dressing, it adapts with the wound, handling more fluid under heavily exudating conditions to help prevent maceration while retaining required moisture under dry conditions to maintain a moist wound environment, which has been shown to enhance wound healing. The dressing is supplied sterile.

*In vitro testing shows that the transparent film provides a viral barrier from viruses 27 nm in diameter or larger while the dressing remains intact without leakage.

| 90614 | 90610, 90612 | 90611, 90613, 90616, 90619 |
| --- | --- | --- |
|  |  |  |

**3M™ Tegaderm™ Foam Adhesive Dressing With Soft Cloth Border (90615):**

3M™ Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border is constructed from a highly absorbent polyurethane foam pad with convenient adhesive border tabs. The border adhesive is not waterproof. The foam pad has a highly breathable film backing which maintains a moist wound environment, prevents wound exudate strike-through and acts as a barrier to outside contamination through the foam pad. The adhesive border tabs are perforated Tegaderm™ film reinforced with soft cloth tape to allow high exchange of both moisture and oxygen. The dressing is supplied sterile and may be custom cut to fit the needs of the user.


**Product Composition**

| Family / Catalog Number | Components | Material |
|---|---|---|
| Tegaderm™ High Performance Foam Adhesive Dressings:<br>90610, 90611, 90612, 90613, 90614, 90616, 90619, 90616D, 90619D | Backing | Polyurethane film adhesive laminate |
| | LAB | LAB (low adhesion backsizing-layer on top of film): Polyurethane/Silicone |
| | Absorbent Pad | Two Layer Nonwoven (Spunlaced rayon/polyester and Rayon/super absorbent fiber blend) |
| | Foam Layer | Polyurethane foam (open cell structure) |
| | Product Liner | Paper |
| | Product Carrier | Paper |

| Family / Catalog Number | Components | Material |
|---|---|---|
| Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border - 90615 | Backing | Polyurethane film/polyester nonwoven/adhesive laminate |
| | LAB | LAB (low adhesion backsizing-layer on top of film): Polyurethane/Silicone |
| | Foam Layer | Polyurethane foam (open cell structure) |
| | Product Liner | Paper |
| | Product Carrier | Paper |

## Intended Use

**3M™ Tegaderm™ Foam Adhesive; High Performance Foam Adhesive Dressing (90610, 90611, 90612, 90613, 90614, 90616, 90619, 90616D, 90619D)**

Tegaderm™ Foam Adhesive dressing (High Performance Foam Adhesive Dressing) is designed to allow easy, one-handed application to difficult body contours, including heels and elbows, without the need for cutting. The dressing is indicated for use as a primary dressing for low to highly exuding, partial and full thickness dermal wounds, including:

- pressure ulcers
- venous leg ulcers
- abrasions
- superficial, partial-thickness burns
- donor sites
- arterial ulcers
- skin tears
- neuropathic ulcers

Additional applications of Tegaderm™ Foam Adhesive dressing (High Performance Foam Adhesive Dressing) include:

- use as a secondary (cover) dressing in conjunction with wound fillers (such as gauze or alginate dressings).
- use under compression wrap systems for venous leg ulcer treatment.

This product is not designed, sold or intended for use except as indicated. Tegaderm™ Foam Adhesive dressing (High Performance Foam Adhesive Dressing) is not intended for use in pressure reduction or as a surgical sponge.

## Intended Use:

**3M™ Tegaderm™ Foam Adhesive; 3M™ Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border (90615)**

The product is conformable and designed for easy application to difficult body contours, such as toes and fingers, without the need for cutting or taping. Tegaderm™ Foam Adhesive dressing (3M™ Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border) is indicated for use as a primary dressing for moderately to highly exuding partial and full thickness dermal wounds, including:

- pressure ulcers
- venous leg ulcers
- abrasions
- superficial, partial thickness burns
- arterial ulcers
- skin tears
- neuropathic ulcers

Additional applications of Tegaderm™ Foam Adhesive Dressing include use:

- as a secondary (cover) dressing for use in conjunction with wound fillers (such as gauze or alginate dressings)
- under compression wrap systems.

This product is not designed, sold or intended for use except as indicated. Tegaderm™ Foam Adhesive Dressing is not intended for use in pressure reduction or as a surgical sponge.

## Product Range

| 3M™ Tegaderm™ High Performance Foam Adhesive Dressing (manufactured in USA and Germany) | | | | | |
|---|---|---|---|---|---|
| **Catalog Number** | **Size/Dimension (total size)** | **Foam Pad size** | **Name/ Descriptor** | **Primary Carton** | **Shipper Box** |
| 90610 | 8,8 cm x 8,8 cm (3 1/2 in x 3 1/2 in) | 5.1 cm x 5.1 cm | Square | 10 each/carton | 4 primary cartons/shipper |
| 90611 | 10 cm x 11cm (4 in x 4 1/2 in) | 7.7 cm x 6.4 cm oval | Small Oval | 10 each/carton | 4 primary cartons/shipper |
| 90612 | 14,3 cm x 14,3 cm (5 5/8 in x 5 5/8 in) | 10.5 cm x 10.2 cm | Square | 10 each/carton | 4 primary cartons/shipper |
| 90613 | 14,3 cm x 15,6 cm (5 5/8 in x 6 1/8 in) | 10.2 cm x 10.7 cm oval | Oval | 5 each/carton | 6 cartons/shipper |
| 90614 | 6,9 cm x 7,6 cm (2 3/4 in x 3 in) | 3.2 cm x 3.8 cm oval | Mini Oval | 10 each/carton | 4 cartons/shipper |
| 90616 (90616D) | 19 cm x 22,2 cm (7 1/2 in x 8 3/4 in) | 14.0 cm x 17.5 cm oval | Large Oval | 5 each/carton | 3 cartons/shipper |
| 90619 (90619D) | 13,9 cm x 13,9 cm (5 1/2 in x 5 1/2 in) | 7.6 cm x 7.6 cm | Heel/Elbow Design | 5 each/carton | 4 cartons/shipper |

| 3M™ Tegaderm™ Foam Adhesive Dressing with Soft Cloth Border (manufactured in US only) | | | | | |
|---|---|---|---|---|---|
| **Catalog Number** | **Size/Dimension** | **Foam Pad size** | **Name/Descriptor** | **Primary Carton** | **Shipper Box** |
| 90615 | 6,9 cm x 6,9 cm (2 3/4 in x 2 3/4 in) | 2.5 cm x 2.5 cm (1.0 in x 1.0 in) | Mini Wrap | 10 each/carton | 4 cartons/shipper |

## GENERAL CHARACTERISTICS

| Parameter | Product Performance | Test Method | Results |
|---|---|---|---|
| Sterility | Sterile unless package is damaged or opened | Sterilization validation | Pass |
| Shelf Life | 2 year minimum shelf life | Bench Study | Pass |
| Wear time | Up to 7 days on skin and compromised skin | Customer evaluation, Clinical study | Confirmed |
| Impermeability to liquids, blood and exudates. May be worn while showering.* | Waterproof, impermeable to liquids like water and body fluids. Allows for showering | ASTM F1670 | Pass |
| Bacterial Barrier * | Physical barrier against bacteria with a size equal or larger than 0,5 µm | ASTM F1819-1998; ASTM F903-1999 Tested with Gram positive cocci (*E. faecalis* and *S. aureus* and Gram negative rods (*E. coli* and *P.* | Pass score for no penetration |
| Viral Barrier * | Physical barrier against blood-borne pathogen virus of size equal to or more than 27nm | ASTM F16 71-1997 The virus tested was smaller in size than Hepatitis B and C viruses and HIV. | Pass score for no penetration |

| Parameter | Product Performance | Test Method | Results |
|---|---|---|---|
| Adhesive Border | Reduces need for tape - less application steps<br><br>Stays in place<br><br>Thin and low profile to minimize edge roll<br><br>Minimal damage to periwound skin<br><br>Adherence to both dry and moist skin conditions<br><br>Ideal for situations where increased securement or longer wear time is needed | Customer evaluation | Confirmed |
| Backing Material | Low friction surface<br>(LAB - low adhesion backsizing-layer) | Bench test | Pass |
| Foam Material | Dressing does not stick to the wound thereby minimizing the disruption of healing tissue<br><br>Provides cushioning for patient comfort | Bench test,<br>Customer evaluation | Confirmed |
| Economics* | Low “in-use” cost based on economic modeling<br><br>(based on US data) | Economic Modeling | Model can be adapted locally |

* Except product 90615

## SAFETY AND SKIN TOLERABILITY (1)

**Tegaderm™ Foam Dressings are tested as a surface device having permanent (> 30 days) contact duration with healthy skin but also breached or compromised surfaces. As such, the guidance suggests that cytotoxicity, sensitization, irritation, subacute/subchronic toxicity, and genotoxicity studies be conducted on patient contacting materials.**

| Parameter | Test Method | Results |
|---|---|---|
| Biocompatibility | ISO 10993-Part 1<br>(biological evaluation of medical devices- evaluation and testing)<br><br>ISO 14971 (application of risk management to medical devices) | In compliance<br><br>In compliance- All documentation complete |
| Skin irritation | ISO 10993-10*<br>HCIPT (Human Cumulative Irritation Patch Test)<br><br>Primary Skin Irritation | Pass |
| Sensitization | ISO 10993-10*<br>Sensitization (GPMT) | Pass |
| Cytotoxicity | ISO 10993-5*<br>Cytotoxicity (MEM) Elution | Safe for intended use |
| Genotoxicity | ISO 10993-3*<br>-In Vitro Chromosomal Aberration Assay | Pass |

| Parameter | Test Method | Results |
|---|---|---|
| | -Bacterial Reverse Mutation Assay | |
| Subchronic Toxicity | ISO 10993-11*<br>90-Day subchronic systemic toxicity study | Pass |

* testing was conducted on a predicate product, and data bridged to the current product according to ISO 10993 part 1.

## SAFETY AND SKIN TOLERABILITY (2)

| Parameter | Product Performance | Test Method | Results |
|---|---|---|---|
| Basic safety/ absence of toxic compounds | Free of:<br>- DEHP<br>- Natural rubber latex<br>- Animal derived products* | Raw Material Information, Formulation, Composition, LCM | Negative- no health hazard compound materials were detected |
| Basic safety/ absence of Substances of Very High Concern | The substances of the REACH SVHC candidate list as of 16th June 2014 are not present at or above 0,1% in Tegaderm™ Foam dressings | Raw Material Information, Formulation, Composition, LCM | confirmed |

* Except product 90615

## FLUID HANDLING CAPACITY

**All 3M™ Tegaderm™ Foam Dressings adapt to changing levels of exudate to maintain moisture balance for optimal wound healing.**
**3M™ Tegaderm™ 90610, 90611, 90612, 90613, 90614, 90616, 90619, 90616D, 90619D**

| Parameter | Product Performance | Test Method | Results* |
|---|---|---|---|
| 24 Hour Fluid Handling Capacity (i.e. sum of MVTR and Absorbency) | High fluid handling capacity, adaptable fluid management | Bench Study in accordance to EN 13726-1 | 17,9 g/10cm²/24h<br><br>53.7 g/10cm²/72h (extrapolated) |
| | High Absorbency | Bench Study in accordance to EN 13726-1 | 6,7 g/10cm² |
| | High MVTR | based on European Standard EN 13726-1 | 11,2 g/10cm²/24h |
| Free Swell Absorptive Capacity | High free swell absorbency | Bench Study in accordance to EN 13726-1 | 60,3 g/100cm² |

| Parameter | Product Performance | Test Method | Results* |
|---|---|---|---|
| Moisture Reactivity | Low MVTR for low moisture conditions<br><br>High MVTR for high moisture conditions<br><br>Moisture Reactivity (difference between high and low MVTR) | Bench Study in accordance to EN 13726-2 | "Upright" MVTR in contact with vapor (to simulate dry wound conditions):<br>980 g/m²/24h<br>(0,9 g/10cm²/24h)<br><br>"Inverted" MVTR in contact with liquid (to simulate heavy exudating wounds):<br>12750 g/m²/24h<br>(12,8 g/10cm²/24h)<br><br>11770 g/m²/24h |
| Adhesion to steel | Adhesion | Bench testing in accordance to 3M TS-234 | 276 g/cm |

* Lot based data

### 3M™ Tegaderm™ 90615

| Parameter | Product Performance | Test Method | Results* |
|---|---|---|---|
| 24 Hour Fluid Handling Capacity (i.e. sum of MVTR and Absorbency) | Moderate fluid handling capacity, adaptable fluid management | Bench Study in accordance to EN 13726-1 | ~3 g/10cm²/24h<br><br>~9 g/10cm²/72h (extrapolated) |
| | Absorbency | Bench Study in accordance to EN 13726-1 | ~2 g/10cm² |
| | MVTR | based on European Standard EN 13726-1 | ~1,3 g/10cm²/24h |
| Swell | Minimal Swell | Bench Testing in accordance to 3M TS-10412 | <10% |
| MVTR | MVTR | Bench Study in accordance to EN 13726-2 | "Upright" MVTR in contact with vapor:<br>635 g/m²/24h<br>(0,6 g/10cm²/24h)<br><br>"Inverted" MVTR in contact with liquid:<br>3605 g/m²/24h<br>(3,6 g/10cm²/24h) |

* Lot based data

## EASE OF USE

| Parameter | Product Performance | Test Method | Results |
|---|---|---|---|
| Application and removal | Easy to apply and remove<br><br>Conforms to difficult body contours<br><br>3M spoke delivery system for easy application<br><br>Can be applied with gloves | Customer evaluation | Confirmed |
| 90615 | Dressing can be used with other 3M wound and skin care products including:<br><br>Skin Protectants<br>• 3M™Cavilon™ No-Sting Barrier Film<br>• 3M™Cavilon™ Durable Barrier Cream<br><br>Wound Fillers and Contact Layers<br>• 3M™Tegaderm™ Alginate<br>• 3M™Tegaderm™ Alginate Ag<br>• 3M™Tegaderm™ Contact<br>• 3M™Tegaderm™ Matrix<br>• 3M™Tegaderm™ Hydrogel<br><br>Wraps<br>• 3M™Coban™ 2<br>• 3M™Coban 2™ Lite | | |
| 90610<br>90612<br>90613<br>90614<br>90616<br>90616D<br>90619<br>90619D | Dressing can be used with other 3M wound and skin care products including:<br><br>Skin Protectants<br>• 3M™Cavilon™ No-Sting Barrier Film<br>• 3M™Cavilon™ Durable Barrier Cream<br><br>Wound Fillers and Contact Layers<br>• 3M™Tegaderm™ Alginate<br>• 3M™Tegaderm™ Alginate Ag<br>• 3M™Tegaderm™ Contact<br>• 3M™Tegaderm™ Matrix<br><br>Wraps<br>• Coban™ 2<br>• Coban™ 2 Lite | | |

# PACKAGING RELATED INFORMATION

## Packaging Composition

Each dressing is packaged into a pouch (immediate wrapper). Several pouches are packaged into a primary box. Then several primary boxes are placed in a corrugated shipper box.

| Packaging Level | Material |
|---|---|
| Pouch:(Immediate Wrapper) | High Density Polyethylene Printed Film |
| Carton: | Paperboard |
| Shipper: | Corrugated box |

## Packaging standards

| Parameter | Product Performance | Norm | Status |
|---|---|---|---|
| Labeling information supplied by manufacturer | Legally correct labeling | EN1041 | In compliance |
| Symbols used for labeling of medical devices | Legally correct symbols used | EN980 and ISO 15233 | In compliance |
| Sterile Barrier System (SBS) | Sterile unless package is damaged or opened | EN ISO 11607- Part 1&2 | In compliance |
| Undesirable components of packaging | Free of substances of very high concern (SVHCs) in >0,1% in weight concentration | EC Regulation 1907/2006 (REACH) for any packaging article as described in directive 94/62/EC from the EU | Stated in supplier contracts |
| Undesirable components of packaging | Free of PVC (polyvinylchloride)<br><br>Free of silica gel<br><br>Totally Chlorine Free bleaching | 3M internal standards | Stated in supplier contracts |
| Undesirable components of packaging | Sum concentration level of Lead, Cadmium, Mercury and Hexavalent Chromium not to exceed 100ppm (by weight) | Article 9 of EC directive 94/62/EC | Stated in supplier contracts |

## CERTIFICATIONS

| Type of Certification | 3M Company Certifications | Certifying Body | Results |
|---|---|---|---|
| Certifications of manufacturing site ISO 13485 | Kamen in Germany is an ISO 13485 certified plant | Certified by DQS (CE0297) | In compliance |
| Certifications of manufacturing site ISO 13485 | Brookings site in the USA is an ISO 13485 certified plant | Certified by BSI (CE0086) | In compliance |

## Additional information:

The information provided in this technical data sheet related to material content represents 3M's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

This document is valid 3 years from the release date.

This Technical Data Sheet is approved by 3M Regulatory Affairs:
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