Comfort Release®

Global Biomedical Technology

TECHNICAL DATA COMPARISON

PEEL + BREATHABILITY TESTING

BACKGROUND

Global Biomedical Technologies, LLC is manufacturing Comfort Release® first aid, acute & advanced wound care products, as well as other medical adhesive devices by incorporating a special proprietary additive (called "OGS") into a medical grade acrylic adhesive. Co-branding customers can choose from several different acrylic adhesives with varying adhesive properties.

The revolutionary Comfort Release® innovation allows the adhesive device to be removed painlessly and trauma-free from the skin. This is accomplished by the application of common rubbing alcohol to turn off the adhesive to skin bond.

This report studied the adhesive properties of one of our medical grade acrylics on stainless steel plates.

Global Biomedical commissioned DermaMed Coatings to perform adhesive property and breathability testing and compare the results to a market leader's similar wound care products.

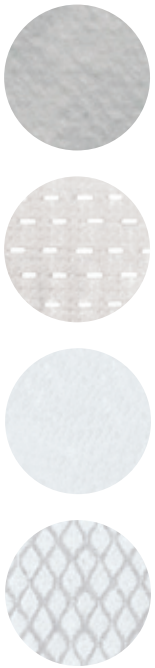
PURPOSE

The purpose of this report is to describe the results of peel adhesion measurements (with and without the application of isopropyl or rubbing alcohol) in accordance with DMT-PSTC-1 standards, and breathability test measurements by following ASTM-E96 standards. The studies were done on adhesive products identified by DermaMed Coatings Company, LLC as DM-2270, DM-4053, DM-4305 and DM-8029, and 3M™ Transpore™ and 3M™ Tegaderm™ adhesive products.

SCOPE

The scope of the testing included the evaluation of peel adhesion results off stainless steel panels with and without the application of isopropyl alcohol (OTC 70% rubbing alcohol). Breathability was observed by moisture vapor transmission rate (MVTR) testing upright at 98° with 50% relative humidity. This report includes details about planning and sampling, pertinent test procedures and results.

MATERIAL DESCRIPTION

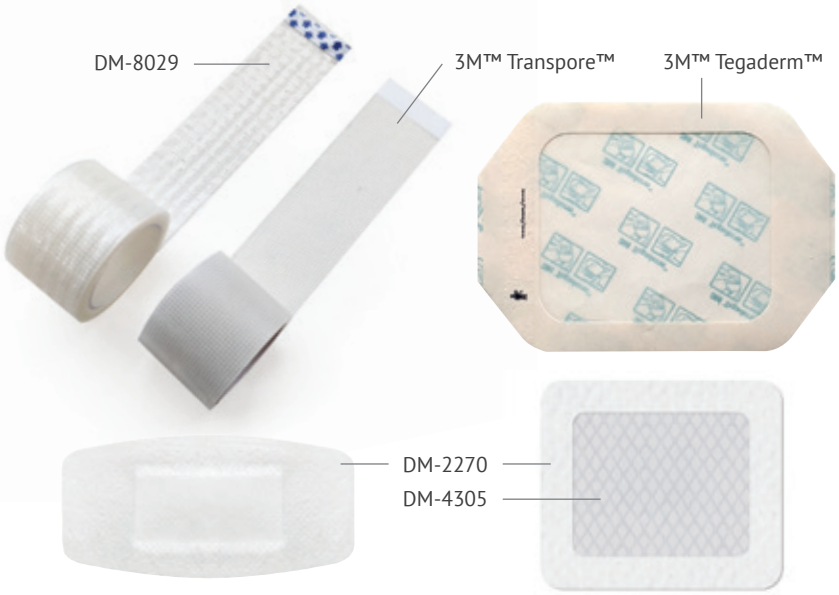


DM-2270 is a film used in Comfort Release® products that consists of a nonwoven polyurethane fabric coated on one side with a medical grade, pressure sensitive acrylic adhesive blended with the OGS additive.

DM-8029 is a film used in Comfort Release® products that consists of a bilateral tear, polypropylene film, laser coated on one side with medical grade pressure sensitive acrylic adhesive blended with the OGS additive and then laser perforated.

DM-4053 is a is a polyester-based thermoplastic polyurethane film supported by a 2 mil polyethylene carrier. It is coated on one side with a medical grade, pressure sensitive acrylic adhesive with the OGS additive and supplied on a silicone coated one-side release liner.

DM-4305 is a thin polyurethane (transparent window) film coated on one side with a low tack pattern coated, medical grade pressure sensitive acrylic adhesive to create a highly breathable, transparent window dressing. OGS is not included.



TEST METHOD DESCRIPTION

PEEL ADHESION DMT-PSTC-1 TEST PROTOCOL

The four adhesive coated films identified as DM-2270, DM-4053, DM-4305 and DM-8029, along with the 3M™ Transpore™ and Tegaderm™, were peeled off of stainless steel panels after a one minute dwell period.

Ten samples of each product were cut into 1" wide strips and applied to the stainless steel with a four and a half pound roller. After the appropriate dwell period, the samples were peeled off the plates at 180˚, at a rate of 12in/min in accordance with DMT-PSTC-1 protocol.

Ten additional samples of DM-2270, DM-4053 and DM-8029 were tested after the application of 70% isopropyl alcohol (OTC, rubbing alcohol). The test protocol included a 1 min dwell time, followed by wetting the outside film surface with isopropyl alcohol and waiting an additional five seconds.

Additionally, both the DM-4305 and 3M™ Tegaderm™ polyurethane films were backed with a 2 mil polyester film single coated with a 1.5 mil silicone adhesive system for required stability. Neither of these products had the isopropyl alcohol applied to them.

MOISTURE VAPOR TRANSMISSION RATE (MVTR) ASTM-E96 TEST PROTOCOL

All products were die cut to 3" x 3" circles and applied to water filled test cups and placed in a temperature and humidity-controlled chamber. The test conditions were 98˚F, 50% relative humidity and the cups were placed in the upright position. Weight loss due to vapor transmission through the test specimens was tested over a standard 28 hour time period.

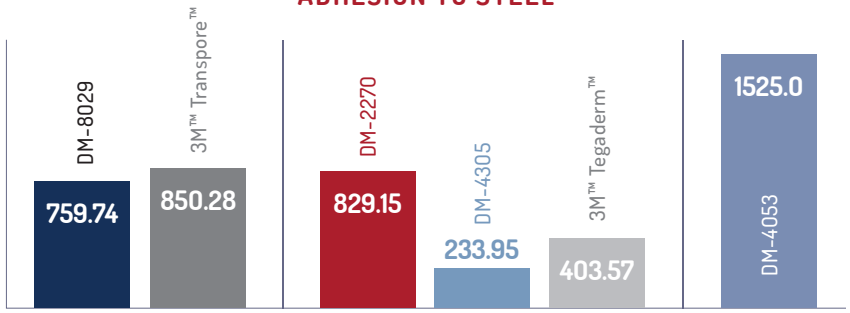
The MVTR test measured the weight of the samples at 4, 8 and 16-hour intervals. Twenty samples of each product were tested.

The Comfort Release® transparent polyurethane material (DM-4305) demonstrated a MVTR of 1776g/m^2/24hr compared to a MVTR of 439g/m^2/24hr for 3M™ Tegaderm™ (a similar thin polyurethane material). The Comfort Release® high tack, thin polyurethane material (DM-4035) demonstrated a MVTR of >260g/m^2/24hr.

PEEL TEST RESULTS WITHOUT RUBBING ALCOHOL – WITH 1 MINUTE DWELL TIME

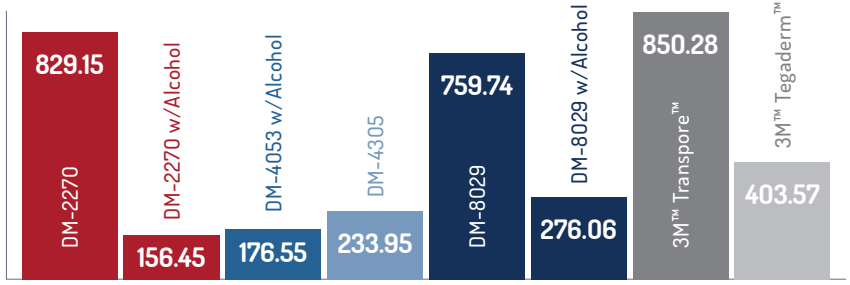
PEEL ADHESION TO STEEL (g/in)						
TEST NO.	DM-2270	DM-4053	DM-4305	DM-8029	3M™ TRANSPORE™	3M™ TEGADERM™
AVERAGE	829.15	1525.00	233.95	759.74	850.28	403.57
MAXIMUM	925.40	1850.00	323.80	835.50	958.10	492.80
MINIMUM	685.60	1475.00	141.70	631.00	714.10	317.90
STANDARD DEVIATION	77.17	50.50	55.67	65.03	76.24	59.42

ADHESION TO STEEL



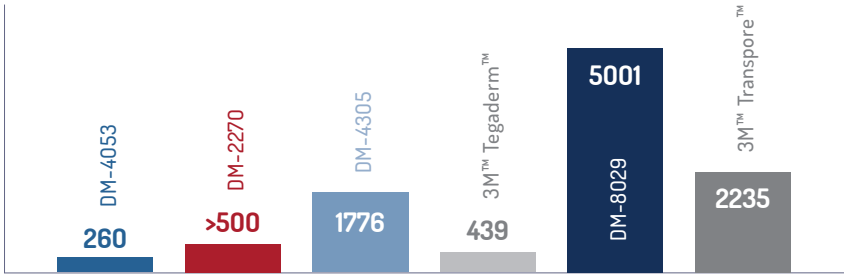
Average Peel Value (g/in)

PEEL TEST RESULTS WITHOUT AND AFTER APPLICATION OF RUBBING ALCOHOL SWIPED THE OUTSIDE SURFACE OF THE FILM



Average Peel Value (g/in)

MVTR RESULTS



g/m²/24hr

The Comfort Release® nonwoven polyurethane material (DM-2270) demonstrated a MVTR of >500g/m²/24hr. The Comfort Release® laser perforated, polypropylene material (DM-8029) demonstrated a MVTR of 5001g/m²/24hr compared to a MVTR of 2235g/m²/24hr for 3M™ Transpore™ (a similar polypropylene material).

RESULTS

In standardized adhesive peel testing, there were high peel values (or high tack adhesion) of the Comfort Release® products on stainless steel. When the 70% isopropyl alcohol was applied to the Comfort Release® materials the peel values on steel were reduced up to 89%. (Results show average peel values of 829g/in reduced to 156g/in, 759g/in reduced to 276g/in and 1525g/in reduced to 176g/in.)

All of Comfort Release® materials demonstrate high moisture vapor transmission rates indicating high breathability. In a comparison testing of similar products, Comfort Release® products were up to 4x more breathable than 3M™ products.

CONCLUSION

Based on peel testing on stainless steel, Comfort Release® products should adhere to the skin at least as well (if not better) than 3M comparable products; yet release more easily when the acrylic adhesive bond is "switched off" with common rubbing alcohol.

These results indicate Comfort Release® Tapes are twice as breathable as 3M™ Transpore™ and Comfort Release® Transparent Dressings are four times as breathable as 3M™ Tegaderm™.

COMFORT RELEASE® CURRENT PRODUCTS

BORDERED FOAM AND SACRAL FOAM DRESSINGS

Strong adhesive is in border, not on foam pad. Recommended wear time is 3 to 7 days. Removes painlessly by swiping the border with common rubbing alcohol. Edges will not roll up.

BORDERED TRANSPARENT FILM DRESSINGS

Strong adhesive in the border with a pattern coated acrylic adhesive in the window. Occlusive and waterproof. Moisture vapor transmission rate (MVTR) is more than 4x the market leader.
Recommended wear time is 3 to 7 days. Removes painlessly by swiping the white outside border with rubbing alcohol.

TAPES

Adhesion comparable to the market leader. Moisture vapor transmission rate (MVTR) is more than 2x the market leader. Removes painlessly by swiping the outside with rubbing alcohol. Available in multiple sizes, including single patient short rolls. Water resistant.

BANDAGES

Removes painlessly by swiping the outside with rubbing alcohol. Available in multiple sizes and quantities.
Water resistant.

DRAPES FOR POST-SURGICAL VACUUM USE

Adhesion is comparable to other vacuum drapes and sealing strips. Removes painlessly, trauma-free and much faster with the application of rubbing alcohol. Available in one size.

Visit comfortrelease.com/where-to-buy for more product details and where to buy. Rubbing alcohol may be required to be purchased separately (see package label).

Dedicated to Patsy Carter-Rattigan — our #1 patient who graciously volunteered to test Comfort Release® samples during our development.

Our Mission is to improve the clinician and patient experience by providing high quality acute and advanced adhesive wound care products with skin injury prevention solutions.

Our Vision for the lives we touch is to have a compassionate experience with a painless and trauma-free adhesive use and which is easily implemented everywhere care is provided.

We developed the Comfort Release® technology to help people of all ages who have experienced the discomfort or injury associated with the removal of bandages, tapes, dressings, ECG electrode pads, negative pressure wound therapy drapes and other medical adhesive products.

Comfort Release®

A Global Biomedical Technology Company

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Visit comfortrelease.com/where-to-buy for more product details and where to buy.
All Comfort Release® products are waterproof or water resistant.